Science and Technology in childhood Obesity Policy

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Start date of project: 1st June 2018 Duration: 54 months

D8.3: Report on the evaluation of the Randomized Control Trial and D8.4: Peer-reviewed publication on the outcomes of the intervention

Note:
D8.3 (Report on the evaluation of the RCT) and D8.4 (Peer-reviewed publication on the outcomes of the intervention) are presented jointly here. The reason for this deviation is due to recruitment delays in the WP8 RCT, resulting in knock-on impacts for follow-up, biological sample analysis and publication. Further details can be found on page 4.

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Dissemination Level

PU	Public	☒
PP	Restricted to other programme participants (including the Commission Services)	
RE	Restricted to a group specified by the consortium (including the Commission Services)	
CO	Confidential, only for members of the consortium (including the Commission Services)	

Abbreviation	Definition
App	Application
BMI	Body mass index
BMI SDS	Body mass index standard deviation score
CEBQ	Child Eating Behaviour Questionnaire
CFPQ	Comprehensive feeding practices questionnaire
GIT	Gastrointestinal tract
ICL	Imperial College London
IOTF	International Obesity Task Force
JCA	Data Sharing and Joint Controller Agreement
KEEP	The Keeping Foster and Kin Parents Supported and Trained parenting program
mHealth	Mobile health
MINISTOP	Mobile-based intervention intended to stop obesity in pre-schoolers
ML	More and Less
MCCV-PLS-DA	Monte Carlo cross-validated partial least square-discriminant analysis
MTA	Agreement on the transfer of Human Biological Material
PCA	Principal Component Analysis
PCR	Polymerase chain reaction
PG	More and Less Parent Group (intervention)
PLS-DA	Partial least square-discriminant analysis
RCT	Randomized controlled trial
ROC	Curves, receiver operating characteristic curves
SD	Standard Deviation
ST	Standard Treatment (control)
UIB	University of the Balearic Islands
UMFT	University of Medicine and Pharmacy “Victor Babeș” Timisoara
WHO	World Health Organization

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Table of contents

1 Deliverables 8.3 and 8.4 description

According to the project plan D8.3 listed "Report on the evaluation of the randomized controlled trial (RCT)" was to be delivered on month 44, while deliverable D8.4 listed "Peer-reviewed publication on the outcomes of the intervention" was to be delivered month 45. Due to the delays related to pandemic (see below section "Deviations from initial project planning "), both deliverables 8.3 and 8.4, were postponed to the end of the project. Thus, we jointly report deliverables 8.3 and 8.4, to better show the process of the RCT together with the results.

Deliverable 8.3 is the result of the work in Task 8.3, named "Three-site RCT of an early childhood obesity intervention: implementation and follow-up" (task leader: CIBER). This task was focused on the evaluation of training, recruitment, and follow-up for the families involved in the RCT. Additional outcomes, included food intake and physical activity measures, as well as biomarkers to support the assessments of the reversibility of the molecular signatures of obesity following the intervention, a validation of dietary reports through the urine metabolomics assays and an analysis of the role of gut hormones and microbiota.

Deliverable 8.4 is the result of the work in Task 8.4, named "Three-site RCT of an early childhood obesity intervention: analysis and evaluation" (task leader: UMF Timisoara). This task brings together all the outcomes of the RCT in an overall analysis and evaluation of: (a) the effect of the intervention on children's anthropometric measures (weight status as primary outcome), child and parental behaviours, and biomarkers; and (b) the generalizability of the findings to other settings and population groups and the feasibility of the intervention with regard to recruitment, attrition, acceptability, and patient satisfaction. This includes interviews with parents and health care providers at the three sites. The deliverable D8.4 named "Peer-reviewed publication on the outcomes of the intervention" shows the analysis of RCT results, however the publication of the results in a peer reviewed journal was not possible due to the Covid-19 related delays.

Deviations from initial project planning

The Covid-19 pandemic led to a temporary suspension of the RCT within in the STOP-project. The suspension delayed the recruitment of families, data collection, delivery of the intervention and consequently data analysis. For deliverable 8.4, we are able to report on primary outcomes after 9 months for all the families; however, the long-term follow-up at 15 and 21 months will be extended beyond the final date of the STOP project.

Due to the delayed recruitment and follow-up, the biological samples collected were not assessed at the time of deliverable 8.3 and 8.4. The samples will be processed as per protocol; however, the results will be analysed together with the other outcomes of the intervention beyond the final date of the STOP project.

Due to necessary internal review by the legal office in each institution (ICL, KI, UMFT, UIB), there was a delay in finalization of the Data Sharing and Joint Controller Agreement (JCA) and the Material Transfer Agreement for the transfer of Human Biological Material (MTA). Despite starting procedures in July 2022, a signed agreement was not in place (per 24th November 2022), therefore the analysis reports country level statistics for results.

A peer review publication at the time of this deliverable was not possible due to delays in the project, leading to incomplete data analysis. The publication of results will be extended beyond the final date of the STOP project in one or more publications.

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2 Peer review publication title page

A randomized controlled trial for overweight and obesity in pre-schoolers - an intervention within the STOP project: Nine months outcomes of the More and Less Europe study

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Trial registration: ClinicalTrials.gov NCT03800823; 11 Jan 2019.

Keywords: children, family, mHealth, obesity, overweight, treatment

3 Abstract

Background: Childhood overweight and obesity is a significant public health issue with negative impact on quality of life. Interventions addressing preschool-aged children with obesity and overweight could presently be the best time to alleviate the health burden of obesity later in life. Treating childhood obesity is difficult and very few countries use standardized treatments. Therefore, effective approaches that are feasible for both health care providers and families are needed. Thus, the overall aim of this study was to assess the acceptance and effectiveness of a parent support program (the More and Less, ML) for the management of overweight and obesity followed by a mobile phone based program (mHealth), the MINISTOP application (app) in a socially diverse population of families with preschool age children.

Methods/design: A two-arm, parallel design randomized controlled trial recruiting 2-to 6-year-old children with overweight and obesity from Romania, Spain and Sweden was conducted. Families that consented to participate were randomized to the ML parent group (PG) or to standard treatment (ST) in a 1:1 ratio after baseline assessments. The ML program, consisted of 10-weekly group sessions, focused on evidence-based parenting practices, followed by a previously validated MINISTOP app, for 6-months, as a continuous support for healthy eating and physical activity behaviours. The primary outcome was change in child weight status (body mass index standard deviation score, BMI SDS) after 9-months. Secondary outcomes were: waist circumference, eating behaviour (Child Eating Behaviour Questionnaire), parenting behaviour (Comprehensive Feeding Practices Questionnaire), physical activity (ActiGraph wGT3x-BT), dietary patterns (based on metabolic markers from urine and 24h dietary recalls), epigenetic and gut hormones (fasting blood samples), and the overall acceptance of the program (evaluation forms, semi-structured interviews).

Results A total of 304 2-to 6-year-old children with overweight and obesity and their families participated in the study, in Romania (n=84, PG=44, ST=40), in Spain (n=90, PG=45, ST=45) and in Sweden (n=130, PG=64, ST=66). In Romania, dropout rates were 27.3% for PG and 25.0% for ST; in Spain, 8.8% for PG and 15.5% for ST; while in Sweden, were 15.6% for PG and 9.1% for ST. According to the country level analyses, in Romania, from baseline to 9-month follow-up, BMI SDS changed from 3.0 (1.1) to 2.3 (1.3) ($p<0.001$) in the PG, and from 3.3 (1.2) to 3.0 (1.1) ($p=0.008$) in ST. In Spain, BMI SDS in the PG changed from 3.4 (1.1) to 3.1 (1.3) ($p=0.034$) and in ST from 3.4 (0.9) to 3.3 (1.1) ($p=0.397$). In Sweden, BMI SDS for the PG changed from 2.7 (0.9) to 2.5 (0.9) ($p<0.001$), and in ST from 2.6 (0.7) to 2.5 (0.7) ($p<0.109$). In Romania, a clinically relevant reduction of 0.5 in BMI SDS from baseline to 9 months was observed in 46.9% children in the PG and in 26.7% children in ST; in Spain, 20% children in the PG and 13.6% in ST and in Sweden, 53.7% children in PG and 33.3% in ST ($p< 0.01$). The delivery of the ML program was appreciated, and the content well accepted by families and group leaders in the three countries. The adjustment to the online format during the pandemic was also well received. The MINISTOP app worked best in Sweden where 75.5% of families that had participated in the parent group sessions used the app, in Spain 64.4%, while in Romania 28.6% used the app. The Swedish families also used the app more to register their child's eating and physical activity habits.

Conclusion: The culturally adapted intervention (ML parent program and MINISTOP app) was accepted by families and caregivers in all three countries: Romania, Spain, and Sweden. Our preliminary results show that the ML program was effective in improving children's weight status in all countries (within group analyses). In Romania, a significant decrease in BMI SDS was also seen in the standard treatment group. Still, analyses of aggregated data are necessary to establish the effect of the intervention and its potential to be implemented into routine care as a structured weight management program for young children.

4 Background and aim section

According to the World Health Organization (WHO), childhood obesity is one of the serious public health challenges of today's society (1). In 2019, approximately 50 (24-89) million girls and 74 (39-125) million boys worldwide were classified as having obesity (2). The WHO European Regional Obesity Report 2022 shows that almost 60% of adults have overweight and obesity and nearly one in three children (29% of boys and 27% of girls) in the WHO European Region (3). These statistics are concerning as it has been found (4) that the overwhelming majority of 3-year-olds with obesity had overweight or obesity in adolescence. Thus, there is a need for evidence-based treatment programs in the pre-school years to reduce the prevalence of overweight and obesity later in childhood. Such programs are still lacking. According to a systematic review by Colquitt et al. (5) for children less than six years of age, multicomponent interventions (i.e., diet, physical activity, and behavioural interventions) seem to be effective at treating overweight and obesity. However, the authors highlighted that evidence is limited (5). Furthermore, the WHO supports and recommends comprehensive and meaningful actions on obesity in all countries, as shown in the 2022 Acceleration Plan to support front-runner countries in the implementation of the recommendations, development and evaluation of national plans which are tailored towards country needs in order to help meet global targets (6).

The pathways from early diagnosis to high-quality treatment in the health care systems are not straightforward and differ between countries. Prevention, diagnosis, and treatment of obesity in children is usually done by paediatric teams of the primary health care centres and by nurses in Sweden (7); by family physicians, and specialist paediatricians in Romania (8); and paediatricians and nurses in Spain (9). Despite the usual good intentions of paediatric teams (doctors and nurses) to address the overweight or obesity in children, child's excess weight tends to be a sensitive topic, especially if the parents themselves have overweight or obesity (10). In addition, the healthcare recipients may hold negative attitudes toward the paediatricians after they were informed on their children obesity (11). Thus, focusing on obesity is difficult for several reasons, including concerns about how the message would be perceived by both the parents and the children (12). Other systemic barriers are the lack of time and excessive workloads of paediatric health care staff, the lack of educational materials, the limited access to specialists, the lack of collaboration with other health care professionals and the lack of awareness on the part of administrators of the importance of the problem (13). Therefore, there is a need for better understanding the barriers and facilitators; describing the attitudes and feelings of health care teams in communicating and discussing overweight and obesity in children with their parents, exploring perceived barriers and facilitators of the health system with the goal of providing effective care to address a successful treatment of obesity in children (14).

Socioeconomic status and ethnic/foreign background have been recognized as one of the key predictors of risk for the development of obesity in childhood as these may lead to great inequities (15). Treatment effectiveness may be affected by family-level factors including attitudes to overweight, understanding of the causes of weight gain and motivation to make and maintain family-level changes in health behaviours (15). Therefore, interventions should be culturally and socially sensitive, avoid stigma, encourage motivation, recognize barriers, and reinforce opportunities and be achievable within the family's time and financial resources, making focus on social disparities in paediatric obesity treatment a high priority for future research (15).

The most effective weight management programs in the pre-school age include support to parents (16–18). The support is often delivered in groups and include skills training in evidence-based parenting practices to support lifestyle changes in children. In Sweden, one of few effective obesity treatments for children aged 4-

6 years old, the More and Less (ML) parent program was developed (16,19). The initial ML program was evaluated in a comprehensive randomized controlled trial (RCT) in Stockholm County in Sweden. The program outperformed the standard care; reduction in weight status was -0.3 vs -0.07 in body mass index standard deviation score (BMI SDS) after 12 months (16). Furthermore, children in the parent program were five times more likely to reach a clinically significant reduction of ≥0.5 in BMI SDS (16).

An innovative element of the initial ML study was the provision of follow-up phone calls after the parent program. The results showed that child weight status continued to improve if parents received phone calls – BMI SDS -0.54 compared to -0.11 for no follow-up calls (16). Our results confirm previous reports that families need prolonged support to maintain the effects on child weight status (17,20). While phone-calls were successful, this approach did not suit all families, and some parents did not answer the calls. Compliance was also a challenge in the group receiving standard care; 70% of the families cancelled their visits (16). Mobile health (mHealth) could help to overcome this challenge. To provide most optimal care and thus improve equity, mHealth offers promise. To date, most of the treatment interventions for overweight and obesity use face-to-face delivery methods. mHealth is increasingly being used for promoting healthy habits and as treatment of many types of health conditions and diseases. The unanimous use of smartphones makes the use of mHealth an option for boosting the effects of obesity treatment programs without face-to-face or phone meetings (21). The MINISTOP application (app) has previously been validated with positive effects on a composite score composed of body composition, diet, and physical activity variables (5). Of relevance, this effect was more evident among children with a higher body mass index (22).

In order to better understand the metabolic mechanisms that drive weight gain, epigenetics and gut hormones were intensely researched (23,24). Despite attention during last years for involvement in transmitting obesity risk to offspring and in the heritable regulation of gene expression without altering their coding sequence (24–26), these findings need to be confirmed and further explored in young children. Another field of interest for obesity is the gastrointestinal tract (GIT), which is involved in anorectic and orexogenic gut hormones, signals to influence appetite and liver adipose (27). However, evidence of the role of GIT hormones in overweight and obesity among young children is sparse.

A major challenge in the management of obesity in both adults and children is understanding what people eat. Most dietary assessment methodologies use methods of self-reported food intake, which has large misreporting error, and is difficult to apply in children (28,29). Metabolomic methodology of dietary assessment using urine validated in adults have been developed (30), but adapting the method to children is challenging.

To the best of our knowledge, no previous multi-country study has tested the feasibility, acceptance and effectiveness of a parent support program combined with a continuous support through mHealth to manage overweight and obesity in 2- to 6-year-old children. Thus, the aim of the ML Europe study was to do this in a socially diverse population of families in 3 countries (31) The specific aims were:

- to determine the effectiveness on child weight status (BMI SDS) of a 10-week parent support program delivered in groups focusing on evidence-based parenting practices (the ML program) followed by a mHealth program for 6-months (the MINISTOP application, app) for overweight and obesity in preschool-aged children.
- to assess change in secondary outcomes: waist circumference, child eating behaviour, parental feeding practices, and physical activity.

- to assess epigenetic mechanisms and physio-pathological processes underlying childhood obesity including the role of gut hormones.
- to assess and validate child food intake with metabolic markers in urine metabolomics.
- to evaluate the feasibility of recruitment (facilitators and barriers), attrition and acceptability of the intervention and standard treatment and the overall acceptance of overweight and obesity management according to patients and care providers.

Our main hypothesis was that the intervention (the ML program followed by the MINISTOP app for boosting) will be more effective in decreasing children's weight status (BMI SDS) as primary outcome, improving food habits, eating behaviours, and physical activity as well as parental feeding practices (secondary outcomes) compared to standard care. Another study hypothesis was that the intervention would produce changes in urinary metabolites, which would serve as biomarkers of the nutritional outcomes. We also hypothesized that the parent support program and the mHealth intervention would be well accepted by families.

5 Methods section

Study design

The study protocol was published in 2019 (31). In brief, the ML Europe is a two-arm parallel design randomized controlled trial (RCT) comparing overweight and obesity treatments in 2- to 6-year-old children in three countries (Romania, Spain and Sweden). Following baseline assessments, participants were randomized into the intervention and control group in a 1:1 ratio. The intervention group received a 10-week parent support program (the ML program) which focused on evidence-based parenting practices (16,19) followed by a previously validated 6-month mHealth program (the MINISTOP app, Principal Investigator: M Löf) to support healthy lifestyle changes (22,32). The control group received standard treatment as offered in the country of participation. Assessments were conducted at 10 weeks, 9 months, 15 months, and 21 months post-baseline. The recruitment, treatment approaches, methods, randomization and blinding have been previously described in the study protocol (31).

Participants and recruitment

In total, we aimed to include 300 families (n = 100 in Romania, Spain, and Sweden, respectively). Inclusion criteria were: (1) children between 2-6 years old that had overweight or obesity as classified by international cut-offs (33); and (2) at least one parent was able to communicate in Romanian, Spanish, or Swedish depending on the country of participation. Exclusion criteria: (1) underlying medical condition(s); (2) child had already started treatment for overweight or obesity; and (3) parents who did not own a smartphone compatible with the MINISTOP app (i.e., version 10.0 or higher for iOS (year 2016) or version 5.0 or higher for Android (year 2014)).

Recruitment followed a standardized protocol for all countries. In Romania, family physicians and paediatricians were involved to hand out information about the study to families with 2- to 6-year-olds with overweight or obesity. Parents who wanted to learn more about the study were provided with a phone number, email address, web page and Facebook page with information of how to contact the research group. Participants were recruited, as self-referrals, using an official page for the study on Facebook to be shared with specialized groups.

In Spain, families with children who attended weight and height assessments at their paediatricians at primary care health centres and hospitals were asked to participate in the study. If the parents were interested in participating, the paediatrician scheduled a visit within a maximum of seven days to provide them with more detailed information regarding the study and for them to sign the informed consent.

In Sweden, the recruitment methods has been previously described (16,19). Briefly, recruitment was done primarily at primary child health care centres, where all parents of children from birth to 5 years of age are offered free, yearly check-ups. If overweight or obesity was detected the nurse provided a verbal and a short one-page description of the study. If the parent(s) were interested in participating the nurse sent a referral to the research group that sent out more detailed information regarding the study together with a consent letter. After one week, a member from the research team contacted the families to answer any questions that they had. Recruitment was also conducted at secondary health care (i.e., out-patient paediatric clinics). Additionally, self-recruitment was done through newspaper ads as well as by placing posters on primary health care bulletin boards.

For all countries, after fully informing the families, if they still wanted to participate, they sent back the signed consent letter, which was subsequently signed by a member of the research team and a copy was sent back to the family. A time for baseline assessments was then scheduled with the research group.

Randomization and blinding

After the consent form was signed, the participants were randomly allocated to either the intervention group (parent support program and mHealth program) or the control group (standard care as per country) at a 1:1 ratio via a random allocation sequence list (in blocks of three). The sequence list was generated using free software environment for statistical computing and graphics R (version 3.5.1) (34). The random allocation sequence was managed by a person who has no relationship with recruitment or treatment and opaque envelopes were used to ensure concealment. Those assessing the outcomes were blinded to the treatment allocation; however, owing to the nature of the intervention participants were not blind to their allocation.

Intervention – More and Less program and the MINISTOP app

The More and Less parent support program

The More and Less Program has previously been described in the study protocol (31). In brief, the ML program comprised of 10 weekly sessions (1.5 hours/week – table 1) that was culturally adapted for Romanian, Spanish, and Swedish families with preschool aged children with overweight or obesity. Beyond the evidence-based parenting practices, the program included content regarding healthy food habits, physical activity habits, as well as techniques to help parents regulate emotional control. Each session begun with a theoretical introduction to a parenting skill. The focus of the session was discussed and put to practice through role plays and homework assignments. To facilitate the implementation of the ML program a manual where the sessions are described with precise instructions to the group leaders (2 per group) was used. The parents also received a manual summarizing what was discussed during each session. For parents who were unable to attend sessions, the parental manual was sent home to the family and the family was contacted by phone for a brief review of the session. To facilitate session attendance the time and location for the groups were planned to suit the parents. Childcare was provided during the sessions. The ML group leaders received an initial four day training in child overweight and obesity management and the ML program, as previously described (31).

Table 1. Session content of the More and Less Program

Session	Content
1	Welcome and overview
2	Food and play: When more? When less?
3	Parents as teachers: cooperation and energy balance
4	Parents as teachers: to teach children new behaviors
5	Rewards and incentives
6	Pre-teaching
7	Parents as teachers: limit setting strategies
8	Power struggles: to avoid and to handle them
9	More support – Less stress
10	Summary: parenting, food and play – to prepare for the future

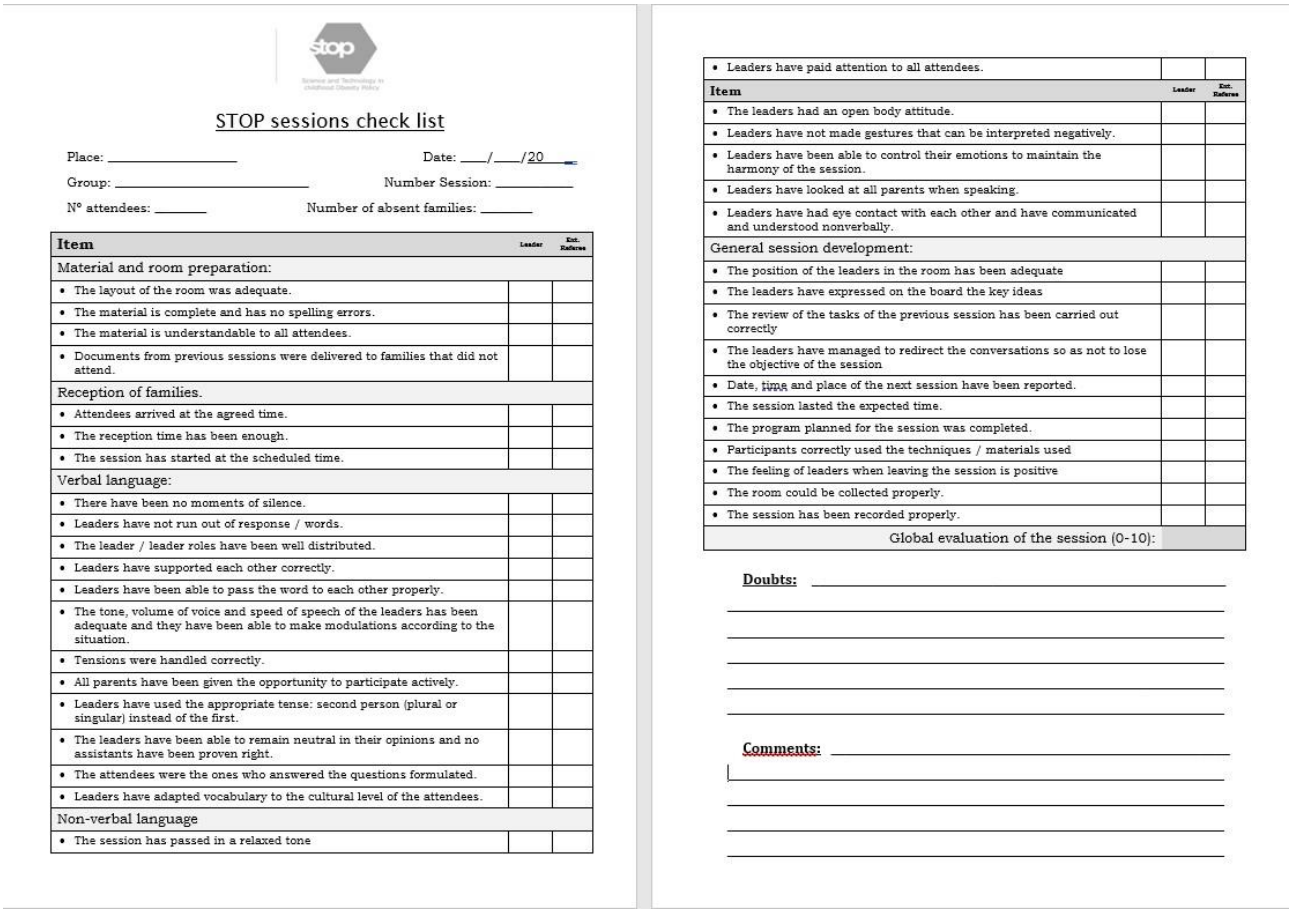
Staff training

The training of Spanish and Romanian group leaders was successfully conducted in Timisoara, Romania, December 2-5, 2018, and provided by the ML program developers Paulina Nowicka and Anna Ek (KI, Sweden), as shown in figure 1a and b. In Sweden, the training of group leaders was conducted in 2018 and in 2021. During the training, the sessions of the program were thoroughly discussed, and the group leaders were trained to deliver the program by acting as group leaders while the other participants acted as parents.

1a  1b 

Figure 1a and 1b: Training of Romanian and Spanish ML group leaders in Timisoara, Romania, 2018.

The training of group leaders was continued with external supervision by the Swedish team at KI, during the first parent group, in all countries. The supervision was conducted after each weekly session. Group leaders recorded and watched the group sessions reflecting over questions they had been given in advance (figure 2). In Sweden, the supervisor also watched the video recordings. This was not possible for the Spanish and Romanian team due to the language barrier. Instead, to make sure the supervision covered all necessary parts, the supervisor followed a checklist for each session. During supervision, group leaders were asked what they thought about the group session they had had, what went well, what was challenging and how was this handled, how they had used feedback and suggestions from previous supervision (session 2-10). If they thought the content of the program was understood by the parents or was there something they needed to explain more. If all parents participated actively, what did the group leaders do to encourage those that were less active? How did they handle late arrivals and families that did not turn up to the groups? The supervision ended by reviewing the next week's session to see if the group leaders had any questions on the content of the manual and how they had planned to lead the next session. In Romania and Spain, two group leaders were supervised and conducted the groups- In Sweden, six group leaders conducted the groups, five received supervision within the study, one was already a certified group leader.



STOP sessions check list

Place: _____ Date: ___/___/20___

Group: _____ Number Session: _____

N° attendees: _____ Number of absent families: _____

Item	Leader	Ext. Referee
Material and room preparation:		
• The layout of the room was adequate.		
• The material is complete and has no spelling errors.		
• The material is understandable to all attendees.		
• Documents from previous sessions were delivered to families that did not attend.		
Reception of families.		
• Attendees arrived at the agreed time.		
• The reception time has been enough.		
• The session has started at the scheduled time.		
Verbal language:		
• There have been no moments of silence.		
• Leaders have not run out of response / words.		
• The leader / leader roles have been well distributed.		
• Leaders have supported each other correctly.		
• Leaders have been able to pass the word to each other properly.		
• The tone, volume of voice and speed of speech of the leaders has been adequate and they have been able to make modulations according to the situation.		
• Tensions were handled correctly.		
• All parents have been given the opportunity to participate actively.		
• Leaders have used the appropriate tense: second person (plural or singular) instead of the first.		
• The leaders have been able to remain neutral in their opinions and no assistants have been proven right.		
• The attendees were the ones who answered the questions formulated.		
• Leaders have adapted vocabulary to the cultural level of the attendees.		
Non-verbal language		
• The session has passed in a relaxed tone		

• Leaders have paid attention to all attendees.		
Item	**Leader**	**Ext. Referee**
• The leaders had an open body attitude.		
• Leaders have not made gestures that can be interpreted negatively.		
• Leaders have been able to control their emotions to maintain the harmony of the session.		
• Leaders have looked at all parents when speaking.		
• Leaders have had eye contact with each other and have communicated and understood nonverbally.		
General session development:		
• The position of the leaders in the room has been adequate		
• The leaders have expressed on the board the key ideas		
• The review of the tasks of the previous session has been carried out correctly		
• The leaders have managed to redirect the conversations so as not to lose the objective of the session		
• Date, time and place of the next session have been reported.		
• The session lasted the expected time.		
• The program planned for the session was completed.		
• Participants correctly used the techniques / materials used		
• The feeling of leaders when leaving the session is positive		
• The room could be collected properly.		
• The session has been recorded properly.		
Global evaluation of the session (0-10):		

Doubts: _____

Comments: _____

Figure 2: Checklist for parent group sessions for group leaders to fill out.

The MINISTOP app

The MINISTOP app was developed and evaluated in a population based study with preschool aged children (Principal Investigator: Marie Löf) and has been previously described in detail (22,32). Briefly, MINISTOP comprises of an extensive program of information and push notifications for a healthy diet and physical activity in pre-school aged children. Over a 6-month period, 12 themes were covered (table 2) (31). A new theme was introduced bi-weekly, with parents being alerted by a push notification. Every theme was divided into three parts (general information; advice; and strategies to change unwanted behaviour). Through the app, parents had the ability to register their child's consumption of sugar sweetened beverages, candy, ice-cream, fruits, vegetables, physical activity, and sedentary behaviour. Parents received feedback on the registered parameters at the end of every week. Reminder messages were sent to parents if they had not used the app for a couple of days (31). Two days before the final session of the ML program, parents received an email with a username and password for the MINISTOP app as well as a text message with a link to download the app. At the final session, the ML group leaders ensured that all parents were able to download the app and sign in. Thereafter, they explained how the app worked to the parents and answered their questions.

Table 2. MINISTOP app content

Theme	Content
1	Healthy foods in general
2	Breakfast
3	Healthy small meals
4	Physical activity and sedentary behaviour
5	Candy and sweets
6	Fruits and vegetables
7	Drinks
8	Eating between meals
9	Fast food
10	Sleep
11	Foods outside the home
12	Foods at special occasions

Cultural adaptation of the More and Less manual and the MINISTOP app

Prior to the staff training, the More and Less manual and MINISTOP app contents were translated from Swedish to English (KI, Sweden), and from English to Romanian (UMTF, Romania) and to Spanish (CIBER, Spain). This translation was not only a simple translation to another language. It was a cultural adaptation changing tips on cooking and healthy food habits to include the most common foods in the different countries. For example introducing common Mediterranean foods in the recipes; using well-known dishes in the Southern Europe (i.e.: "Spanish *paella"*, "*pulpo a la gallega"*, "*empedrado de lentejas"*) which have no exactly translation in other languages and cultures; it was necessary to use fish species characteristic for country instead of those from Scandinavia; as well as it was necessary to substitute the usual fat used for cooking: virgin olive oil instead of butter, as usual in the Southern Europe. Family activities recommended was also slightly adjusted as the countries different climates make outdoor activities in Sweden slightly different than in Romania and Spain, especially during winter. In Romania, specific foods were introduced, such as "*sarmale*", "*tocanita*", stuffed peppers or polenta, while fish is not a common food in children 2-6 years of age in Romania. Food labelling was also something that was adjusted to suit the labelling for guidance to healthy food choices available in the specific country. Overall, no difficulties were declared by the participants to understand the content of the manuals, showing the wide feasibility of its use.

Control group – standard treatment

The weight management offered to the control group followed the standard care procedures for each country. In Romania and Spain, the control group received an evaluation of a one-day food frequency questionnaire, as well as a 30-minute consultation with a physician that was a specialist in childhood nutrition, where healthy lifestyle recommendations were made. The parents also received a hand-out which provided general recommendations for healthy food and physical activity in 2- to 6-year-olds. Furthermore, in Romania the children were re-evaluated after 3 months during a 15-minute consultation. In Sweden, the control group received standard care according to the Action plan for overweight and obesity for Stockholm County (35). Children with overweight and children with obesity younger than 4 years received support from their child health care nurse. Children older than for 4 years with obesity were followed in an outpatient paediatric clinic with yearly visits to a paediatrician and follow-up visits to a paediatric nurse, approximately 5 visits (30 minutes in duration) per year (16). The treatment focused on supporting the family in creating

healthy dietary and physical activity habits for the child. Children were also referred to dieticians, psychologists, or physiotherapists.

Measurements

Outcome measures were collected at baseline, 10 weeks, 9 months, 15 months, and 21 months post baseline. Table 3 presents when outcome measures were assessed, and the instruments used to assess child and parental behaviours.

Table 3. Socio-demographic characteristics and outcome measures collected at different time points.

	Measure	Baseline	10 weeks	9 months	15 months	21 months
Child						
Weight/height	Measured by health professionals	x	x	x	x	x
Waist circumference		x	x	x	x	x
Date of birth	Child background questionnaire	x		x	x	x
Country of birth		x				
Sex		x				
Health status		x		x	x	x
Family structure		x		x	x	x
Daycare		x		x	x	x
Visits to health care regarding weight		x		x	x	x
Screen time		x		x	x	x
Breakfast consumption		x		x	x	x
Juice/soda/cordial intake		x		x	x	x
Eating behavior	Child Eating Behavior Questionnaire			x	x	x
Physical activity/sedentary behavior	ActiGraph wGT3x-BT accelerometer			x		
Food intake	Urine samples and 24hr dietary recalls			x		
Epigenetic and metabolic markers	Fasting blood samples			x		
Parent						
Weight/height	Parent questionnaire	x		x	x	x
Date of birth		x				
Country of birth		x				
Sex		x				
Education level		x				
Health status		x		x	x	x
Occupation status		x		x	x	X
Income		x		x	x	x
Social and economic support from network		x		x	x	x
Perceived level of comfortable life		x		x	x	x
Parenting behavior	Comprehensive Feeding Practices Questionnaire	x		x	x	x
Feasibility, attrition, and acceptability	Semi-structured interviews		x			
Health care professionals						
Feasibility, attrition, acceptability	Semi-structured interviews		x			

Socio-economic background

At baseline parents were asked to fill out a background questionnaire for the child and themselves. Questions for the parent included: health status, sociodemographic factors (education level, foreign background, income level), and social support. For the child, questions included: country of birth, health status, family

structure and lifestyle related questions such as food and screen time behaviours (31). Parental education level was categorized as: Elementary 0-9 years; High-school 0-12 years and University degree. Parental foreign origin was defined as the parent and or both grandparents being born abroad. Monthly income is presented as salary categories for each country each country, in Romania in lei, in Spain and Sweden in Euro.

Anthropometric measures

Anthropometric measures were assessed as per the published study protocol (31). In brief, children's weight and height were measured to the nearest 0.1 kg and 0.1 cm. A fixed stadiometer was used to measure height and weight was measured with the children wearing light clothing. BMI was calculated as weight (kg) divided by height (m) squared. BMI SDS, the primary outcome, was then calculated using age and gender specific reference values according to IOTF (33). Waist circumference was measured at the mid-point between the lower rib and iliac crest to the nearest 0.1 cm using a non-elastic tape measurer. Weight, height, and waist circumference were measured three times and mean values derived. All children were measured in a standardized manner by trained health care professionals using calibrated instruments.

In addition to change in BMI SDS, we report on the clinical significance of the weight status change using cut-offs for a clinically significant reduction of ≥0.25 and ≥0.5 of BMI SDS, both associated with improvements in metabolic profile in children and adolescents, the larger reduction the better metabolic improvements (36,37).

Eating behaviour

The children's eating behaviour was assessed using the Child Eating Behaviour Questionnaire (CEBQ) (38). CEBQ includes 35 items on eating styles comprising eight factors related to the risk of obesity. Parents rated each behaviour on a five-point Likert scale (`never´, `rarely´, `sometimes´, `mostly´, and `always´ for items 1 to 13 and `disagree´, `slightly disagree´, `neutral´, `slightly agree´, and `agree´ for items 14 to 49). Mean scores for each subscale were calculated. This questionnaire has been found to have high internal reliability and good validity (38,39).

Feeding practices

The Comprehensive Feeding Practices Questionnaire (CFPQ) was used to measure parenting behaviour (40). The CFPQ is a parent-report instrument, designed to measure feeding practices of parents of children aged 2-8 years. It contains 49 items comprising 12 factors including both *protective* feeding practices such as monitoring, environment encourage balance and variety, involvement, modelling and teaching about nutrition as well as *negative* feeding practices such as emotion regulation, food as reward, child control, pressure, restriction for health and restriction for weight control. Parents rate each behaviour on a five-point Likert scale (`never´, `rarely´, `sometimes´, `mostly´, and `always´). The CFPQ has previously been validated in several countries, for example in Spanish for Brazilian pre-schoolers (41).

Physical activity and sedentary behaviour

The ActiGraph wGT3x-BT accelerometer (ActiGraph Corp, Pensacola, USA, www.actiGraphcorp.com) was used to assess physical activity and sedentary behaviour over seven consecutive 24 hour periods. The ActiGraph was attached the child's non-dominant wrist and worn at all times, except for water-based activities (e.g., showering/bathing or swimming). The recorded movements are not analysed at the time of this deliverable. It will be used to estimate time in various activity levels based on appropriate cut-offs for pre-school children.

Biological markers and food intake

If accepted by the child and caregiver, urine and blood samples were collected at baseline and 9 months to be able to assess metabolites of food intake (from urine), epigenetic markers and gut hormones (from fasting blood samples) as described in the published study protocol (31). For each child three urine samples were collected, 6 and 3 days prior to the day of measurement and at the morning of the measurement. The blood samples were taken by experienced nurses and children had been given pain reducing cream on the area for the blood sampling to reduce any discomfort.

The Dietary Metabotype Score which relate to diet adherence and components of food will be validated against a 24-h dietary recall in forthcoming analysis. The 24-h dietary recall was collected for all children providing a urine sample and covered the day prior to the visit to the research group when the urine was collected. For children attending preschool, teachers filled out a food diary for food intake not covered by the parental report for the day of the 24h recall.

Assessment of feasibility, attrition, and acceptability of the intervention

Feasibility of recruitment

Feasibility of recruitment was assessed through semi-structured interviews with parents and healthcare professionals by trained research staff. Interviews focused on identifying facilitators and barriers in the communication about the young child's overweight, in order to initiate weight management. During the interviews a set of questions were asked to all participants. However, follow-up questions were based on individual responses. The questions were tested in pilot interviews with both parents and health care professionals. The interviews were recorded and fully transcribed.

Attrition and acceptability of the intervention (ML and MINISTOP) and standard care

Attrition was measured through attendance of treatment, either to clinical visits as for ST or to sessions as for PG. Treatment hours was calculated as 0,5h (30min) per visit for ST and 1,5h (90min) per session for PG. Acceptability of treatment was assessed through evaluation forms distributed at the last group session of the ML program. Parents answered to what extent they agreed on 16 statements with the response options: 1 = not at all, 2 = sometimes, 3 = most often, 4 = completely. For MINISTOP, use and acceptability of the app was assessed through brief telephone interviews after 3-months as well as objective data of how many had downloaded, used, and made registrations in the app. A thorough qualitative evaluation of the parents' perceptions of the ML program, the MINISTOP app and the standard treatment is currently being organized, thus this data will be included in a future peer-reviewed publication.

Adverse events

Adverse events have been monitored, reported, and handled appropriately. The risks imposed by this research project were deemed to be low, i.e., the burden of the experiments for the research subjects was limited. It is important to note that blood samples collected in the study were optional and not a criterion for participation. However, blood samples were taken by experienced nurses and a pain reducing cream was used to reduce any discomfort. Urinary samples were not invasive and thus caused no risk to the participants. In addition, the investigators had extensive experience conducting behavioural weight control studies, and active efforts were taken by the research staff to ensure the participating families' safety. Although, not defined as an adverse event but worth noticing, was the psychosocial burden that parents experienced when

made aware about their child's weight status and the sense of guilt that they felt. To handle this, in both individual conversations and in parent group sessions, causes and consequences of obesity were reviewed in a non-judgmental way supporting the parents to strengthen their sense of being in control and being able to support their child. Also, potential impact on the child's self-esteem and the way to talk about body weight and obesity with children, if necessary, was addressed during the ML program and during individual visits if needed (31).

Data management

All collected data was handled as approved by the ethical boards in each country to protect confidentiality. Data was de-identified and entered manually into a database by research staff at the participating site where the data originated from. An identical database was used at each site. To ensure data quality and validity the researchers follow standard operation procedure protocols when entering data. The entered data was double checked by the person entering the data and random checks were performed regularly to ensure data validity. The database is password protected and the access is restricted to researchers with passwords at each study site. Original data forms is stored securely at each study site (31).

Statistical analysis

Descriptive analysis was performed for each country (Romania, Spain and Sweden) are presented here. Main outcome analysis, including statistical significance used SPSS (IBM, Armonk, NY, USA). Main outcome investigated the clinical relevance of results obtained, by inspecting frequency of children that reached BMI SDS reduction cut-offs of 0.25 and 0.5, after 9 months.

Further statistical analysis will be performed for aggregated data from the three countries, as described previously (31). Intention-to-treat analysis using generalized linear mixed models with repeated measures will be used to examine the effects of the intervention on primary and secondary outcomes for the total study population (i.e., all three sites). The link function for the primary outcome (BMI SDS) will be the identity and the Gaussian family (equivalent to a linear regression). In secondary outcomes we will use a Gaussian identity and family link function for waist circumference, physical activity and sedentary behaviour, and a logarithmic link and Poisson family function (equivalent to a Poisson regression) for child eating behaviour and parental feeding practices. A random effect for country will be used to account for the clustered study design. In the models, we will control for relevant covariates such as sex, age, parental weight status, education level, income, and foreign background. Random intercept and a random slope for time will be included in the model to control those non-observed confounders specific to each child that could be constant or vary in time, respectively. Furthermore, interactions between variables will be estimated. If missing values in the outcomes (primary and secondary) are more than 10%, these will be imputed through a two-part model (also known as a model for semi continuous data). Dropout is defined as declined participation and only baseline measure or inclusion was registered. In this model, we would simultaneously estimate the probability of not being missing (first part) and the outcome (second part), using a mixed generalized linear model, in which we would include, as explanatory variables: age, sex, parental weight status, foreign background, educational level, and the random effects which are aforementioned (31).

Accelerometer data will be analysed using R-studio software package GGIR which is specially developed and compatible with GT3x accelerometer in young children.

Statistical tests and analyses of the interaction of phenotypical outcomes with epigenetics were not performed at the time of this deliverable but will be included in a future publication.

Based on power calculations, a total of 300 children were needed (adjusted for dropout) to detect a difference of 0.3 BMI SDS with 85% power at 9-month follow-up between the intervention and control group. These calculations are based on a previous study in this age group (42).

Ethics approval

This trial was approved by the Ethics Committee of Scientific Research in University of Medicine and Pharmacy "Victor Babes", Timisoara, Romania, October 31st, 2018 (25/31.10.2018), the Balearic Islands Ethics Committee, Mallorca, Spain, February 13th, 2019 (IB 3814/18 PI), and the Research Ethics Committee, Stockholm, Sweden, December 11th, 2018 (2018/2082-31/1 and amendments: January 16, 2020, Dnr 2019-05593 and January 28 2021, Dnr 2021-00259). Written informed consent was obtained from all parents/caregivers. The ethics committees approved the consent procedure.

6 Results section

The study population

In summary, a total of 304, 2-to 6-year-old children with overweight and obesity from Romania (total 84, PG 44, ST 40), Spain (total 90, PG 45, ST 45) and Sweden (total 130, PG 64, ST 66) were included in the study. Flow-chart of participants during the study is presented in figure 3. In Romania, dropout rates were 27.3% (12/44) for PG and 25.0% (10/40) for ST; in Spain, 8.9% (4/45) for PG and 15.6% (7/45) for ST; while in Sweden, rates were 15.6% (10/64) for PG and 9.1% (6/66) for ST. Reasons to decline participation were: no time, family reasons, change of family site of residence, manage on their own, don't want to/or wanting to be in group setting, family/personal reason, or no specific reason.

A description of the children in the study population is provided in table 4. In summary: in Romania, children were on average 5.1 years old, 53.6% were girls with a mean BMI SDS of 3.3, 26.2% having overweight, 20.2% obesity and 53.6% severe obesity. In Spain, children were on average 5.4 years old, 66.7% were girls and mean BMI SDS was 3.4 with 3.3% had a normal weight at study start (three children), 7.8% overweight, 14.4% obesity and 74.4% severe obesity. In Sweden, children were younger than in Spain and Romania, on average 4.7 years old, 68.5% were girls and mean BMI SDS was 2.7 with 1.5% having normal weight (two children) at study start, 29.2% overweight, 30.0% obesity and 39.2% severe obesity.

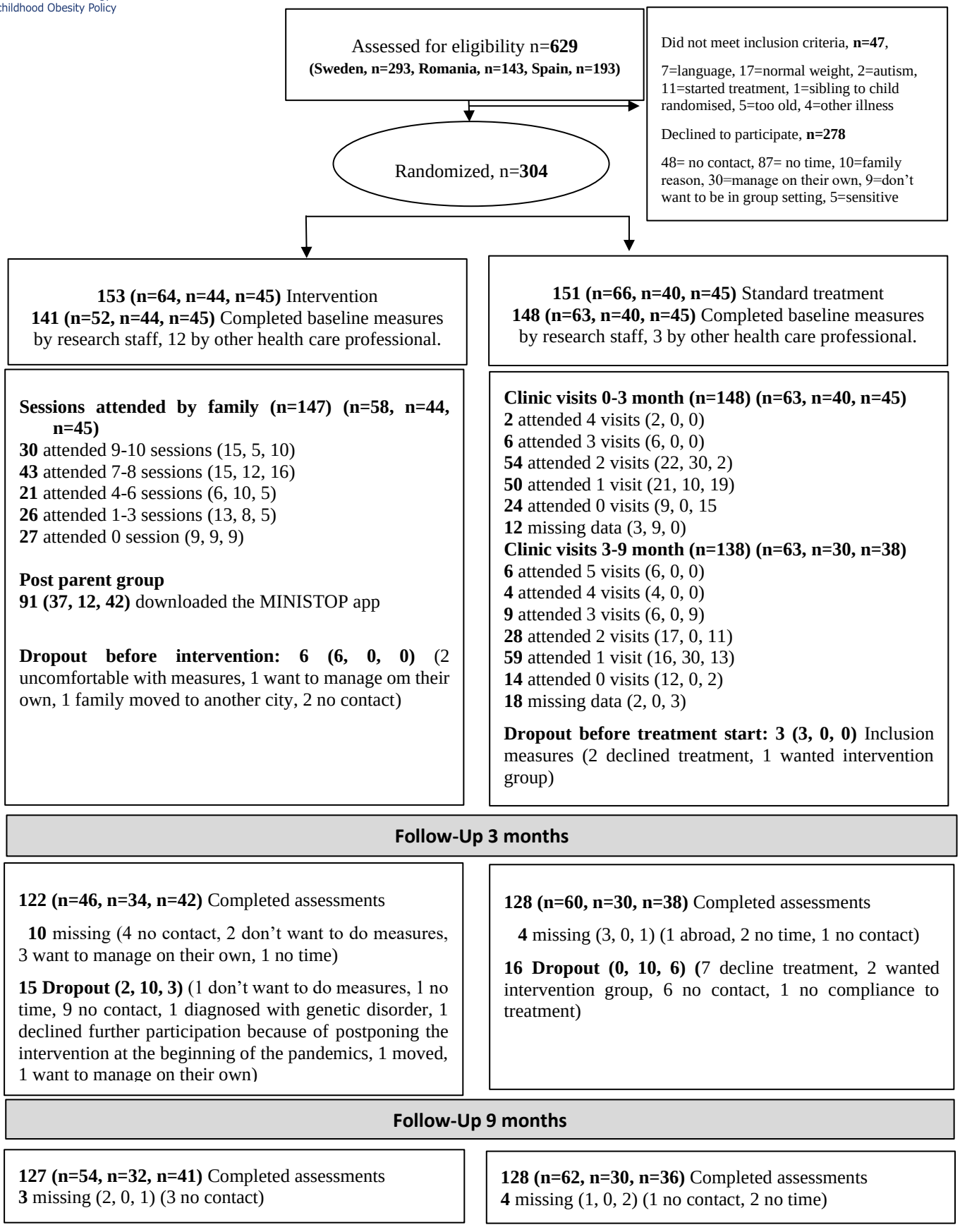


Figure 3. Flowchart for study participants in Sweden, Romania, and Spain

Table 5 describes the characteristics of participating mothers in the study. In summary: in Romania, mothers were on average 35.6 years, none were of foreign background, 62.1% had a university degree, 30.3% were categorized as having a normal weight, 42.4% as having overweight, 18.2% as having obesity and 9.1 % as having severe obesity. In Spain, mothers were on average 40.0 years, 33.3% were of foreign origin, 9.0% had a university degree, 25.3% were categorized as having a normal weight, 29.3% as having overweight, 21.3% as having obesity and 24.0 % as having severe obesity. In Sweden, mothers were on average 37.4 years, 39.4% were of foreign origin, 59.1% had a university degree, 37.4% were categorized as having a normal weight, 35.8% as having overweight, 15.4% as having obesity and 11.4 % as having severe obesity.

Table 6 describes the characteristics of participating fathers in the study. In summary: in Romania, fathers were on average 38.5 years, none were of foreign background, 43.2% had a university degree, 6.6% were categorized as having a normal weight, 38.6% as having overweight, 38.6% as having obesity and 15.9% as having severe obesity. In Spain, fathers were on average 41.6 years, 32.0% were of foreign origin, 23.3% had a university degree, 10.2% were categorized as having a normal weight, 44.1% as having overweight, 30.5% as having obesity and 15.3 % as having severe obesity. In Sweden, fathers were on average 40.3 years, 37.2% were of foreign origin, 44.6% had a university degree, 19.3% were categorized as having a normal weight, 52.9% as having overweight, 20.2% as having obesity and 7.6 % as having severe obesity.

Change in weight status (primary outcome) per country

Table 7 reports changes in primary outcome, BMI SDS, BMI and waist circumference for each country and figure 4-6 visualize the changes in BMI SDS at each study site comparing the intervention and the control group. No between group differences were seen but all countries reported within group differences for PG and in Romania also for ST. To summarize the results: in Romania, mean (sd) BMI SDS changed from 3.0 (1.1) to 2.3 (1.3) ($p<0.001$) in the PG from baseline to 9-month follow-up, and from 3.3 (1.2) to 3.0 (1.1) ($p=0.008$) in ST. In Spain, BMI SDS changed from 3.4 (1.1) to 3.1 (1.3) in the PG ($p=0.034$) and in ST from 3.4 (0.9) to 3.3 (1.1) ($p=0.397$). In Sweden, BMI SDS for the PG changed from 2.7 (0.9) to 2.5 (0.9) ($p<0.001$), and in ST from 2.6 (0.7) to 2.5 (0.7) ($p<0.109$).

Table 8 reports the clinically relevant improvements of BMI SDS. In Romania, a majority, over 50%, of the children reached a clinically relevant reduction of weight status of 0.25 after 9 months in both treatment groups and close to 50% reached the cut-off of 0.5 in the PG. In Spain, most of the PG children reached the 0.25 cut-off after 9 months. In Sweden, about 54% of the PG children reached the 0.25 improvement after 9 months and 33% the 0.5 cut-off. For both cut-offs there was a significant difference between the treatment groups.

Table 4. Baseline descriptive of the study population children from Romania, Spain and Sweden

Children	Romania			Spain			Sweden		
	All	Parent group	Standard treatment	All	Parent group	Standard treatment	All	Parent group	Standard treatment
	n=84	n=44	n=40	n=90	n=45	n=45	n=130	n=64	n=66
Age (years), mean (sd)	5.1 (1.2)	5.4 (1.1)	4.7 (1.2)	5.4 (1.4)	5.3 (1.5)	5.4 (1.5)	4.7 (1.3)	4.8 (1.1)	4.6 (1.0)
Sex (girl), n (%)	45 (53.6)	23 (52.3)	22 (55.0)	60 (66.7)	30 (66.7)	30 (66.7)	89 (68.5)	40 (62.5)	49 (74.2)
BMI SDS, mean (sd)	3.3 (1.2)	2.98 (1.1)	3.25 (1.18)	3.4 (0.98)	3.4 (1.05)	3.4 (0.91)	2.7 (0.8)	2.7 (0.9)	2.6 (0.7)
BMI, kg/m2, mean (sd)	22.4 (3.9)	22.0 (3.6)	22.8 (4.1)	23.7 (3.5)	23.6 (3.6)	23.7 (3.5)	20.6 (2.2)	20.8 (2.3)	20.4 (2.0)
WC, cm, mean (sd)	69.0 (11.7)	66.8 (16.3)	70.7 (10.5)	72.8 (9.6))	71.4 (10.0)	74.2 (9.2)	64.9 (6.8)	66.4 (7.7)	63.7 (5.8)
Weight category									
Normal weight, n (%)	0	0	0	3 (3.3)	2 (4.4)	1 (2.2)	2 (1.5)	1 (1.6)	1 (1.5)
Overweight, n (%)	22 (26.2)	10 (22.7)	12 (30.0)	7 (7.8)	3 (6.7)	4 (8.9)	38 (29.2)	19 (29.7)	19 (28.8)
Obesity, n (%)	17 (20.2)	14 (31.8)	3 (7.5)	13 (14.4)	6 (13.3)	7 (15.6)	39 (30.0)	17 (26.6)	22 (33.3)
Severe obesity, n (%)	45 (53.6)	20 (45.5)	25 (62.5)	67 (74.4)	34 (75.6)	33 (73.3)	51 (39.2)	27 (42.2)	24 (36.4)

Weight category according to IOTF (33). Five children had a normal weight at baseline but had borderline overweight at the time of inclusion in the study.

Table 5. Baseline descriptive of mothers from Romania, Spain and Sweden.

Mothers	Romania			Spain			Sweden		
	All	Parent group	Standard treatment	All	Parent group	Standard treatment	All	Parent group	Standard treatment
	n=66	n=36	n=30	n=77	n=42	n=32	n=121	n=60	n=61
Age, years, mean (sd)	35.6 (5.9)	35.2 (5.6)	35.9 (6.3)	40.0 (6.3)	39.7 (6.1)	40.7 (6.2)	37.4 (5.8)	36.9 (6.8)	37.9 (4.5)
BMI, kg/m^2, mean (sd)	27.0 (5.7)	26.7 (5.3)	27.4 (6.3)	28.9 (6.5)	29.3 (7.2)	28.3 (5.6)	27.8 (5.9)	28.0 (6.5)	27.7 (5.4)
Weight category*, n (%)	n=66	n=36	n=30	n=75	n=42	n=32	n=126	n=61	n=65
Normal weight, n (%)	20 (30.3)	11 (30.6)	9 (30.0)	23 (30.7)	9 (27.3)	14 (33.3)	46 (37.4)	21 (36.2)	25 (38.5)
Overweight, n (%)	28 (42.4)	17 (47.2)	11 (36.7)	21 (28.0)	13 (39.4)	8 (19.0)	44 (35.8)	22 (37.9)	22 (33.8)
Obesity, n (%)	12 (18.2)	5 (13.9)	7 (23.3)	27 (36.0)	10 (30.3)	17 (40.5)	19 (15.4)	8 (13.8)	11 (16.9)
Severe obesity, n (%)	6 (9.1)	3 (8.3)	3 (10.0)	4 (5.3)	1 (3.0)	3 (7.1)	14 (11.4)	7 (12.1)	7 (10.8)
Foreign origin, n (%)	0	0	0	26 (33.3)	12 (28.6)	14 (38.9)	50 (39.4)	17 (27.9)	33 (50.0)
Education, n (%)	n=66	n=36	n=30	n=78	n=42	n=36	n=127	n=61	n=66
Elementary 0-9 years, n (%)	11 (16.6)	4 (11.1)	7 (23.3)	38 (48.7)	19 (45.2)	19 (52.7)	6 (4.7)	3 (4.9)	3 (4.5)
High-school 0-12 years, n (%)	14 (21.2)	5 (13.9)	9 (30.0)	33 (42.3)	19 (45.5)	14 (38.9)	46 (37.4)	19 (31.1)	27 (40.9)
University degree, n (%)	41 (62.1)	27 (75.0)	14 (46.7)	7 (9.0)	4 (9.5)	3 (8.3)	75 (59.1)	39 (63.9)	36 (54.5)
Income (per month), n (%)	n=64	n=36	n=28	n=75	n=40	n=35	n=126	n=60	n=66
Category 1, n (%)	11 (17.2)	7 (19.4)	4 (14.3)	15 (20)	6 (15.0)	9 (25.7)	23 (18.3)	8 (13.3)	15 (22.7)
Category 2, n (%)	23 (35.9)	11 (30.6)	12 (42.9)	10 (13.3)	6 (15.0)	4 (11.4)	9 (7.1)	1 (1.7)	8 (12.1)
Category 3, n (%)	17 (26.6)	10 (27.8)	7 (25.0)	32 (42.7)	18 (45.0)	14 (40.0)	18 (14.3)	9 (15.0)	9 (13.9)
Category 4, n (%)	9 (14.1)	6 (16.7)	3 (10.7)	9 (12.0)	3 (7.5)	6 (17.1)	23 (18.3)	13 (21.7)	10 (15.2)
Category 5, n (%)	3 (4.7)	2 (5.6)	1 (3.6)	9 (12.0)	7 (17.5)	2 (5.7)	21 (16.7)	12 (20.0)	9 (13.9)
Category 6, n (%)	1 (1.6)	0 (0.0)	1 (3.6)				32 (25.3)	17 (28.4)	15 (22.8)

Salary categories: In Romania cat 1 < 1263; cat 2: 1263 – 2526; cat 3: 2526 – 3020; cat 4: 3020 – 4283, cat 5: 4283 – 6050, cat 6: > 6050 lei/month. In Spain cat 1: none; cat 2 < 800; cat 3: 800 - 1400; cat 4: 1400 - 2300; cat 5: >2300 EURO/month. In Sweden cat 1 < 2000; cat 2: 2000 - 2500; cat 3: 2500 - 3000; cat 4: 3000 - 3500, cat 5: 3500 - 4000, cat 6: >4000 EURO/month.

Table 6. Baseline descriptive of fathers from Romania, Spain, and Sweden.

Fathers	Romania			Spain			Sweden		
	All	Parent group	Standard treatment	All	Parent group	Standard treatment	All	Parent group	Standard treatment
	n=44	n= 28	n=16	n=73	n=41	n=32	n=121	n=60	n=61
Age, years, mean (sd)	38.5 (6.9)	39.1 (6.7)	37.5 (7.5)	41.6 (6.2)	41.3 (6.0)	42.0 (6.6)	40.3 (5.8)	39.7 (5.3)	40.8 (6.3)
BMI, kg/m^2, mean (sd)	30.3 (4.7)	30.1 (4.6)	30.7 (5.1)	30.0 (4.8)	29.5 (3.8)	30.7 (5.8)	28.4 (4.4)	28.7 (4.5)	28.1 (4.4)
Weight category*, n	n=44	n=28	n=16	n=59	n=33	n=26	n=121	n=60	n=61
Normal weight, n (%)	3 (6.8)	2 (7.1)	1 (6.3)	6 (10.2)	2 (6.1)	4 (15.4)	23 (19.3)	11 (19.0)	12 (19.7)
Overweight, n (%)	17 (38.6)	13 (46.4)	4 (25.0)	26 (44.1)	17 (51.5)	9 (34.6)	63 (52.9)	30 (51.7)	33 (54.1)
Obesity, n (%)	17 (38.6)	9 (32.1)	8 (50.0)	18 (30.5)	12 (36.4)	6 (23.1)	24 (20.2)	11 (19.0)	13 (21.3)
Severe obesity, n (%)	7 (15.9)	4 (14.3)	3 (18.8)	9 (15.3)	2 (6.1)	7 (26.9)	9 (7.6)	6 (10.3)	3 (4.9)
Foreign origin, n (%)	0	0	0	24 (32.0)	15 (36.6)	9 (26.5)	45 (37.2)	20 (33.3)	25 (41.0%)
Education, n	n=44	n=28	n=16	n=73	n=38	n=32	n=121	n=60	n=61
Elementary 0-9 years, n (%)	9 (20.5)	3 (10.7)	6 (37.5)	14 (19.2)	9 (21.9)	5 (15.7)	11 (9.1)	5 (8.3)	6 (9.8)
High-school 0-12 years, n (%)	16 (36.4)	10 (35.7)	6 (37.6)	42 (57.6)	21 (51.3)	21 (65.6)	55 (45.5)	26 (43.3)	29 (47.5)
University degree, n (%)	19 (43.2)	15 (53.6)	4 (25.0)	17 (23.3)	11 (26.8)	6 (18.8)	54 (44.6)	29 (48.3)	26 (42.6)
Income (per month), n	n=44	n=28	n=16	n=69	n=38	n=31	n=119	n=58	n=61
Category 1, n (%)	2 (4.5)	2 (7.1)	0 (0.0)	15 (20)	6 (15.0)	9 (25.7)	8 (6.7)	6 (10.3)	2 (3.3)
Category 2, n (%)	14 (31.8)	8 (28.6)	6 (37.5)	10 (13.3)	6 (15.0)	4 (11.4)	5 (4.2)	2 (3.4)	3 (4.9)
Category 3, n (%)	16 (36.4)	9 (32.1)	7 (43.8)	32 (42.7)	18 (45.0)	14 (40.0)	18 (15.1)	6 (10.3)	12 (19.7)
Category 4, n (%)	7 (15.9)	5 (17.9)	2 (12.5)	9 (12.0)	3 (7.5)	6 (17.1)	26 (21.8)	11 (19.0)	15 (24.6)
Category 5, n (%)	2 (4.5)	1 (3.6%)	1 (6.3%)	9 (12.0%)	7 (17.5%)	2 (5.7%)	21 (17.6%)	13 (22.4%)	8 (13.1%)
Category 6, n (%)	3 (6.8%)	3 (10.7%)	0 (0.0%)				41 (34.5%)	20 (34.5%)	21 (34.4%)

Salary categories: In Romania cat 1 < 1263; cat 2: 1263 – 2526; cat 3: 2526 – 3020; cat 4: 3020 – 4283, cat 5: 4283 – 6050, cat 6: > 6050 lei/month. In Spain cat 1: none; cat 2 < 800; cat 3: 800 - 1400; cat 4: 1400 - 2300; cat 5: >2300 EURO/month. In Sweden cat 1 < 2000; cat 2: 2000 - 2500; cat 3: 2500 - 3000; cat 4: 3000 - 3500, cat 5: 3500 - 4000, cat 6: >4000 EURO/month.

Table 7. Results for weight status (BMI SDS primary outcome and BMI) and waist circumference per treatment group (parent group, PG, and standard treatment, ST), and per country at baseline (BL) and after 3 and 9 months (m) using Student's T test for within and between groups analysis.

	Romania					Spain					Sweden				
	BL	3m	9m	BL vs 3m	BL vs 9m	BL	3m	9m	BL vs 3m	BL vs 9m	BL	3m	9m	BL vs 3m	BL vs 9m
	mean (sd)	mean (sd)	mean (sd)	p	p	mean (sd)	mean (sd)	mean (sd)	p	p	mean (sd)	mean (sd)	mean (sd)	p	p
PG	n=44	n=34	n=32			n=45	n=37	n=23			n=64	n=46	n=54		
BMI SDS	3.0 (1.1)	2.7 (1.0)	2.3 (1.3)	**0.001**	**<0.001**	3.4 (1.1)	3.3 (1.1)	3.1 (1.3)	0.465	**0.034**	2.7 (0.9)	2.5 (1.0)	2.5 (0.9)	0.014	**<0.001**
BMI	22.0 (3.6)	21.4 (3.3)	20.9 (3.8)	0.066	0.063	23.6 (3.6)	23.6 (3.6)	23.6 (3.6)	0.342	0.128	20.8 (2.3)	20.5 (2.8)	20.4 (2.7)	0.055	0.053
WC, cm	69.7 (7.5)	69.2 (7.3)	70.4 (8.2)	0.487	0.45	71.4 (10)	72.9 (10.6)	70.6 (11.1)	<0.001	<0.168	66.4 (7.7)*	64.7 (6.4)	64.6 (6.0)	0.981	0.806
ST	n=40	n=30	n=30			n=45	n=34	n=21			n=66	n=60	n=62		
BMI SDS	3.3 (1.18)	3.1 (1.2)	3.0 (1.1)	0.107	**0.008**	3.4 (0.9)	3.3 (1.0)	3.3 (1.1)	0.335	0.397	2.6 (0.7)	2.6 (0.8)	2.5 (0.7)	0.847	**0.109**
BMI	22.8 (4.1)	22.2 (4.1)	22.4 (4.4)	0.089	0.254	23.7 (3.5)	23.7 (3.5)	23.7 (3.5)	0.427	0.301	20.4 (2.0)	20.4 (2.0)	20.4 (2.0)	0.641	0.856
WC, cm	70.1 (10.5)	68.7 (10.1)	70.1 (10.9)	0.54	0.539	74.2 (9.2)	73.5 (9.3)	72.6 (9.3)	0.469	0.168	63.7 (5.8)	65.5 (5.9)	66.4 (6.7)	<0.001	<0.001

Significance levels in bold are within group

* = difference between groups at <0.05

** = difference between groups at <0.01

*** = difference between groups at <0.001

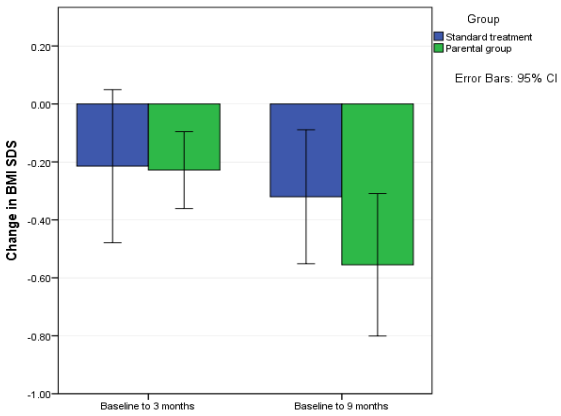


Figure 4. Change in BMI SDS at 3 months and 9 months in Romania for Parental group and Standard treatment with 95% confidence intervals.

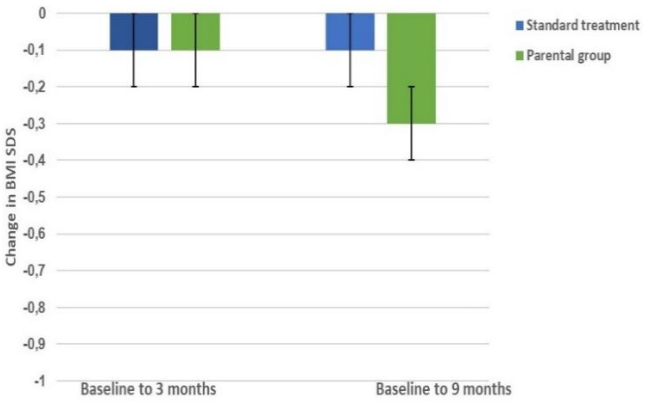


Figure 5. Change in BMI SDS at 3 months and 9 months in Spain for Parental group and Standard treatment with 95% confidence intervals.

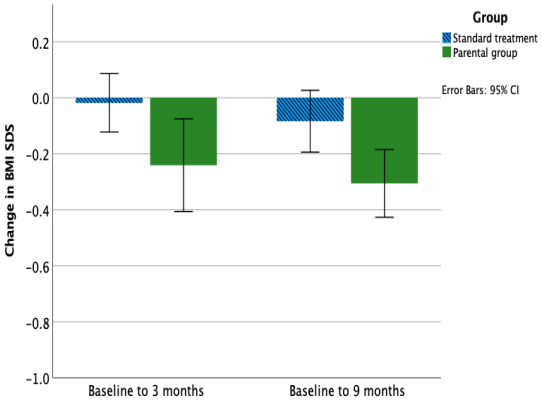


Figure 6. Change in BMI SDS at 3 months and 9 months in Sweden for Parental group and Standard treatment with 95% confidence intervals.

Table 8. Results of clinically relevant reductions of BMI SDS of 0.25 and 0.5 from baseline to 3 and 9 months for the parent group (PG) and standard treatment (ST) in Romania, Spain, and Sweden (using Chi-2 test).

	Romania				Spain				Sweden			
Reduction of 0.25	all	3 months	all	9 months	all	3 months	all	9 months	all	3 months	all	9 months
	n	n (%)	n	n (%)	n	n (%)	n	n (%)	n	n (%)	n	n (%)
PG	34	12 (35.3)	32	20 (62.5)	37	7 (18.9)	25	11 (44.0)	46	18 (39.1)*	54	29 (53.7)*
ST	30	13 (43.3)	30	15 (50.0)	34	6 (17.6)	22	4 (18.2)	60	12 (20.0)	62	20 (32.3)
Reduction of 0.5												
PG	34	6 (17.6)	32	15 (46.9)	37	2 (5.4)	25	5 (20.0)	46	8 (17.4)	54	18 (33.3)**
ST	30	7 (23.3)	30	8 (26.7)	34	4 (11.8)	22	3 (13.6)	60	5 (8.3)	62	7 (11.3)

* = difference between groups at <0.05
** = difference between groups at <0.01
*** = difference between groups at <0.001

Eating behaviour

In order to understand a possible change in the child's eating behaviours (appetitive traits), the mean scores of the factors in the domains Food approach and Food avoidance of the Child eating behaviour questionnaire (CEBQ) are presented in tables 9, 10 and 11, for Romania, Spain and Sweden respectively. Food approach includes factors describing eating behaviours seen in children that enjoy food whilst the factors included in Food avoidance are more often seen in children where food is less appreciated. Food approach has also been associated to a higher weight status in children. In our populations, the children's eating behaviours were stable over time in all three countries (43).

Table 9. Descriptive results of factors in the Food approach and Food avoidance domains of the Child eating behaviour questionnaire, Romania.

Romania	**All**		**Parent group**		**Standard treatment**	
	Baseline	9m	Baseline	9m	Baseline	9m
	n=64	n=46	n=37	n=24	n=27	n=22
	mean (sd)					
Food approach						
Food responsiveness (FR)	2.7 (1.0)	2.6 (0.9)	2.5 (0.9)	2.6 (0.9)	2.9 (1.1)	2.7 (0.9)
Emotional overeating (EOE)	2.1 (0.9)	2.1 (0.8)	1.9 (0.8)	1.9 (0.7)	2.3 (0.9)	2.2 (0.8)
Enjoyment of food (EF)	3.4 (0.8)	3.3 (0.8)	3.2 (0.8)	3.3 (0.8)	3.6 (0.8)	3.4 (0.8)
Desire to drink (DD)	3.0 (1.1)	2.7 (1.1)	2.7 (1.1)	2.6 (1.1)	3.4 (1.0)	2.9 (1.1)
Food avoidance						
Satiety responsiveness (SR)	2.9 (0.7)	2.9 (0.5)	3.0 (0.6)	2.9 (0.6)	2.8 (0.7)	2.9 (0.4)
Slowness in eating (SE)	2.8 (0.7)	2.9 (0.8)	2.8 (0.8)	2.8 (0.9)	2.8 (0.6)	3.0 (0.8)
Emotional under-eating (EUE)	2.6 (0.7)	2.6 (0.7)	2.5 (0.7)	2.6 (0.7)	2.8 (0.7)	2.7 (0.8)
Food fussiness (FF)	3.3 (0.8)	3.3 (0.6)	3.5 (0.7)	3.4 (0.6)	3.0 (0.9)	3.1 (0.6)

* = difference within group at <0.05

Table 10. Descriptive results of the factors in the Food approach and Food avoidance of the Child eating behaviour questionnaire, Spain.

Spain	All		Parent group		Standard treatment	
	Baseline	9m	Baseline	9m	Baseline	9m
	n=77	n=60	n=42	n=33	n=35	n=27
	mean (sd)					
Food approach						
Food responsiveness (FR)	3.5 (1.2)	3.5 (1.2)	3.4 (1.2)	3.3 (1.3)	3.6 (1.2)	3.7 (1.1)
Emotional overeating (EOE)	2.8 (1.1)	2.8 (1.0)	2.8 (1.1)	2.9 (1.1)	2.7 (1.1)	2.8 (0.9)
Enjoyment of food (EF)	4.1 (0.8)	4.2 (0.7)	4.1 (0.8)	4.2 (0.8)	4.2 (0.8)	4.2 (0.6)
Desire to drink (DD)	3.1 (1.2)	2.9 (1.2)	3.1 (1.2)	2.7 (1.2)	3.2 (1.2)	3.0 (1.2)
Food avoidance						
Satiety responsiveness (SR)	2.3 (0.8)	2.1 (0.8)	2.3 (0.8)	2.1 (0.8)	2.3 (0.9)	2.1 (0.8)
Slowness in eating (SE)	2.5 (1.1)	2.4 (1.0)	2.5 (1.0)	2.3 (0.9)	2.6 (1.2)	2.6 (1.1)
Emotional under-eating (EUE)	2.8 (1.1)	2.8 (1.1)	2.9 (1.0)	2.9 (1.1)	2.6 (1.2)	2.6 (1.0)
Food fussiness (FF)	2.8 (1.0)	2.6 (1.0)	2.9 (1.0)	2.6 (1.1)*	2.6 (1.0)	2.5 (0.9)

* = difference within group at <0.05

Table 11. Descriptive results of the factors in the Food approach and Food avoidance domains of the Child eating behaviour questionnaire, Sweden.

Sweden	All		Parent group		Standard group	
	Baseline	9 m	Baseline	9 ms	Baseline	9 ms
	n=112*	n=90**	n=49	n=38	n=63	n=52
	mean (sd)					
Food approach						
Food responsiveness (FR)	3.1 (1.0)	3.2 (1.0)	3.2 (1.0)	3.3 (0.9)	3.0 (1.0)	3.1 (1.0)
Emotional overeating (EMO)	2.0 (0.7)	2.3 (0.9)	2.1 (0.8)	2.3 (0.9)	1.9 (0.7)	2.3 (0.9)
Enjoyment of food (EF)	4.0 (0.7)	4.0 (0.7)	4.1 (0.7)	4.1 (0.7)	3.9 (0.7)	3.9 (0.8)
Desire to drink (DD)	2.6 (0.9)	2.4 (0.9)	2.5 (1.0)	2.3 (0.7)	2.6 (0.9)	2.5 (0.9)
Food avoidance						
Satiety responsiveness (SR)	2.6 (0.7)	2.5 (0.8)	2.5 (0.8)	2.4 (0.8)	2.7 (0.6)	2.6 (0.7)
Slowness in eating (SE)	2.4 (0.9)	2.3 (0.9)	2.2 (0.9)	2.0 (0.8)	2.6 (0.9)	2.4 (0.7)
Emotional under-eating (EUE)	2.7 (0.9)	2.7 (0.9)	2.5 (1.0)	2.6 (0.8)	2.8 (0.9)	2.8 (0.9)
Food fussiness (FF)	2.8 (0.9)	2.8 (0.9)	2.8 (0.9)	2.9 (0.7)	2.9 (0.9)	2.8 (0.9)

* = difference within group at <0.05

Feeding practices

Mean scores of the subscales of the Comprehensive feeding practices questionnaires (CFPQ) are presented in the tables 12, 13 and 14, for Romania, Spain, and Sweden respectively. For both mothers and fathers, feeding practices appeared stable over time in all three countries. A slight increase was seen in both Romanian and Swedish mothers for the monitoring, modelling and restriction for weight control and health. A similar increase was seen in Swedish fathers. A remarkable increase in monitoring and decrease in giving the child food as reward were seen in Romanian fathers, however, the small sample size at follow-up could have affected these results. In Spain just data from mothers were available; despite it, similar results to those registered in Sweden and Romania were also obtained.

Table 12. Descriptive results of the subscales of the Comprehensive feeding practices questionnaire, Romania

Romania	All		Parent group		Standard treatment	
	Baseline	9 months	Baseline	9 months	Baseline	9 months
	Mean (sd)					
Mothers	n=67	n=48	n=36	n=21	n=31	n=27
Monitoring	3.8 (0.9)	4.0 (0.8)	3.7 (1.0)	4.2 (0.8)	4.0 (0.9)	3.9 (0.9)
Emotional regulation	1.6 (0.7)	1.3 (0.5)	1.5 (0.6)	1.3 (0.5)	1.6 (0.9)	1.4 (0.5)
Food as a reward	2.3 (1.0)	2.3 (0.9)	2.3 (1.0)	2.3 (0.9)	2.3 (0.9)	2.3 (1.0)
Child control	3.3 (0.8)	3.0 (0.7)	3.4 (0.7)	3.0 (0.6)	3.3 (0.9)	3.0 (0.8)
Modeling	3.8 (0.9)	4.0 (0.7)	3.7 (0.9)	3.9 (0.6)	4.0 (0.9)	4.1 (0.8)
Restriction for weight control	3.4 (0.8)	3.6 (0.8)	3.2 (0.6)	3.4 (0.7)	3.6 (0.8)	3.7 (0.8)
Restriction for health	3.9 (0.8)	4.0 (0.7)	3.7 (0.8)	3.9 (0.8)	4.1 (0.6)	4.2 (0.5)
Teaching nutrition	3.9 (0.8)	4.1 (0.7)	3.9 (0.7)	4.1 (0.7)	3.9 (0.8)	4.1 (0.7)
Encourage balance and variety	4.5 (0.5)	4.5 (0.5)	4.5 (0.4)	4.5 (0.3)	4.4 (0.6)	4.4 (0.7)
Pressure to eat	1.8 (0.8)	1.8 (0.8)	1.8 (0.8)	1.9 (0.9)	1.7 (0.8)	1.7 (0.7)
Healthy environment	3.8 (0.8)	3.9 (0.8)	3.8 (0.8)	3.9 (0.7)	3.8 (0.8)	4.0 (0.8)
Involvement	3.8 (0.8)	4.1 (0.7)	3.7 (0.6)	4.2 (0.5)	3.9 (0.9)	4.0 (0.8)
Fathers	n=23	n=11	n=19	n=6	n=4	n=5
Monitoring	3.0 (1.1)	3.9 (0.9)	2.9 (1.1)	4.1 (0.7)	3.5 (0.8)	3.6 (1.1)
Emotional regulation	1.8 (0.7)	1.7 (0.6)	1.8 (0.7)	2.0 (0.6)	1.7 (0.6)	1.3 (0.4)
Food as a reward	2.5 (0.9)	2.0 (1.0)	2.5 (0.9)	2.1 (1.1)	2.4 (1.2)	1.8 (1.0)
Child control	3.2 (0.7)	3.0 (0.5)	3.2 (0.8)	3.0 (0.6)	3.0 (0.4)	3.0 (0.5)
Modeling	3.7 (1.0)	3.5 (1.1)	3.7 (1.0)	3.5 (0.6)	3.6 (1.5)	3.6 (1.5)
Restriction for weight	3.0 (0.8)	3.3 (0.7)	3.0 (0.9)	3.1 (0.8)	3.2 (0.3)	3.6 (0.5)
Restriction for health	3.3 (0.9)	3.8 (0.4)	3.3 (0.8)	3.5 (0.3)	3.4 (1.3)	4.1 (0.3)
Teaching nutrition	3.7 (0.9)	3.9 (0.6)	3.7 (0.9)	3.9 (0.4)	3.7 (0.5)	3.9 (0.8)
Encourage balance and variety	4.1 (0.8)	4.3 (0.8)	4.1 (0.8)	4.1 (0.9)	4.1 (0.5)	4.6 (0.5)
Pressure to eat	1.8 (0.8)	1.8 (0.8)	1.9 (0.8)	2.4 (0.6)	1.3 (0.4)	1.2 (0.2)
Healthy environment	3.7 (0.6)	3.9 (0.6)	3.7 (0.7)	3.9 (0.7)	3.8 (0.2)	4.0 (0.5)
Involvement	3.7 (0.8)	3.9 (1.2)	3.6 (0.9)	4.2 (0.9)	4.2 (0.4)	3.6 (1.6)

* = difference within group at <0.05

Table 13. Descriptive results of the subscales of the Comprehensive feeding practices questionnaire (CFPQ), Spain.

Spain	All		Parent group		Standard treatment	
	Baseline	9 months	Baseline	9 months	Baseline	9 months
	Mean (sd)					
Mothers	n=78	n=62	n=42	n=34	n=36	n=28
Monitoring	3.2 (1.3)	3.5 (1.2)	3.4 (1.4)	3.7 (1.3)	3.0 (1.1)	3.3 (0.9)
Emotional regulation	1.8 (0.9)	1.8 (1.0)	1.9 13.0)	2.1 (1.1)	1.6 (0.6)	1.6 (0.7)
Food as a reward	2.0 (1.0)	2.0 (1.0)	2.1 (1.0)	2.1 (1.0)*	2.0 (1.1)	1.8 (1.0)
Child control	2.5 (0.7)	2.3 (0.7)	2.5 (0.7)	2.3 (0.8)	2.4 (0.7)	2.4 (0.6)
Modeling	4.2 (0.8)	4.3 (0.9)	4.2 (0.8)	4.3 (0.9)	4.3 (0.9)	4.2 (0.8)
Restriction for weight control	3.3 (1.0)	3.5 (1.0)	3.3 (0.9)	3.5 (1.1)	3.4 (1.1)	3.4 (0.9)
Restriction for health	4.0 (1.0)	4.0 (1.1)	4.0 (1.0)	3.8 (1.2)	4.1 (1.1)	4.2 (0.8)
Teaching nutrition	3.9 (0.7)	3.9 (0.8)	3.9 (0.7)	3.8 (0.9)	3.9 (0.8)	3.9 (0.8)
Encourage balance and variety	4.6 (0.5)	4.3 (0.6)	4.6 (0.5)	4.3 (0.7)	4.6 (0.6)	4.3 (0.5)*
Pressure to eat	4.2 (0.6)	4.1 (0.7)	4.1 (0.7)	4.0 (0.7)	4.4 (0.5)	4.1 (0.6)
Healthy environment	3.8 (0.7)	3.9 (0.7)	3.9 (0.7)	3.9 (0.8)	3.8 (0.6)	3.8 (0.6)

Involvement	3.8 (0.8)	3.7 (0.8)	3.6 (0.8)	3.5 (0.8)	4.0 (0.7)	3.9 (0.8)*

* = difference within group at <0.05

Table 14. Descriptive results of the subscales of the Comprehensive feeding practices questionnaire, Sweden.

Sweden	All		Parent group		Standard group	
	Baseline	9 months	Baseline	9 months	Baseline	9 months
	mean (sd)					
Mothers	n=110	n=89	n=48	n=37	n=62	n=52
Monitoring	4.3 (0.7)	4.2 (0.7)	4.3 (0.6)	4.3 (0.5)	4.2 (0.7)	4.2 (0.8)
Emotional regulation	1.7 (0.7)	1.6 (0.6)	1.6 (0.6)	1.7 (0.6)	1.8 (0.7)	1.6 (0.6)
Food as a reward	1.9 (0.9)	1.9 (0.8)	1.8 (0.9)	1.8 (0.8)	2.0 (0.9)	1.9 (0.8)
Child control	2.6 (0.6)	2.4 (0.5)	2.5 (0.6)	2.3 (0.5)	2.6 (0.6)	2.5 (0.6)
Modeling	3.8 (1.0)	4.2 (0.8)	3.7 (0.9)	4.3 (0.7)	3.8 (1.0)	4.1 (0.9)
Restriction for weight control	2.9 (0.7)	3.2 (0.7)	2.9 (0.7)	3.2 (0.7)	2.9 (0.6)	3.1 (0.7)
Restriction for health	3.7 (0.8)	3.9 (0.7)	3.8 (0.8)	3.9 (0.7)	3.7 (0.7)	3.9 (0.8)
Teaching nutrition	3.4 (0.9)	4.0 (0.8)	3.5 (0.9)	4.0 (0.7)	3.4 (0.9)	4.1 (0.8)
Encourage balance and variety	4.2 (0.7)	4.4 (0.6)	4.2 (0.6)	4.4 (0.5)	4.3 (0.7)	4.3 (0.7)
Pressure to eat	2.0 (1.0)	1.9 (0.8)	1.9 (0.9)	1.9 (0.8)	2.2 (1.0)	2.0 (0.8)
Healthy environment	3.8 (0.9)	3.9 (0.8)	3.9 (0.9)	4.1 (0.7)	3.7 (0.9)	3.8 (0.8)
Involvement	3.1 (1.0)	3.3 (0.9)	3.1 (1.1)	3.2 (1.0)	3.1 (0.9)	3.4 (0.8)
Fathers	n=100	n=77	n=44	n=35	n=56	n=44
Monitoring	4.0 (0.8)	4.1 (0.6)	4.1 (0.6)	4.0 (0.5)	4.0 (0.9)	4.1 (0.7)
Emotional regulation	1.7 (0.6)	1.7 (0.6)	1.7 (0.7)	1.8 (0.5)	1.6 (0.6)	1.6 (0.6)
Food as a reward	2.0 (0.9)	1.9 (0.9)	2.0 (1.0)	2.1 (0.9)	2.0 (0.9)	1.9 (1.0)
Child control	2.5 (0.6)	2.4 (0.6)	2.5 (0.6)	2.4 (0.5)	2.5 (0.6)	2.5 (0.7)
Modeling	3.6 (1.0)	3.7 (0.8)	3.5 (1.1)	3.6 (0.8)	3.7 (0.9)	3.8 (0.8)
Restriction for weight	2.9 (0.7)	3.1 (0.6)	3.0 (0.7)	3.1 (0.6)	2.8 (0.7)	3.1 (0.6)
Restriction for health	3.7 (0.8)	3.9 (0.6)	3.8 (0.9)	3.9 (0.6)	3.5 (0.6)	3.9 (0.6)
Teaching nutrition	3.3 (0.9)	3.6 (0.7)	3.3 (0.9)	3.6 (0.7)	3.2 (0.8)	3.7 (0.7)
Encourage balance and variety	3.9 (0.8)	4.1 (0.6)	3.9 (0.8)	4.0 (0.6)	3.9 (0.8)	4.1 (0.6)
Pressure to eat	2.3 (0.9)	2.1 (0.8)	2.1 (0.8)	2.0 (0.7)	2.5 (1.0)	2.2 (0.9)
Healthy environment	3.8 (0.7)	3.9 (0.7)	4.0 (0.7)	4.0 (0.7)	3.6 (0.7)	3.8 (0.7)
Involvement	3.0 (0.9)	3.1 (0.9)	2.9 (0.8)	3.0 (0.8)	3.1 (1.0)	3.2 (1.0)

* = difference within group at <0.05

Accelerometer data

Accelerometer data were collected for seven consecutive days of activity from 43 children at baseline and 13 children at 9 months follow-up in Romania. In Spain, 80 children at baseline and 55 at 9 months follow up. In Sweden, data were collected from 88 children at baseline and 63 at 9 months follow-up.

Analysis to interpret the children's physical activity will be performed beyond the project's STOP date.

Collection of biological samples

Table 15 and 16 present the total number of plasma, buffy coat, and urine samples collected at baseline and at the 9-months follow-up for children in both the intervention and control group.

Table 15. Total number of plasma, buffy coat, and urine samples collected at baseline in all three countries.

Baseline	All	Romania	Spain	Sweden
Plasma	105	30	21	54
Buffy coat	103	30	21	52
Urine sample day 1	204	35	80	89

Urine sample day 2	206	36	80	90
Urine sample day 3	206	35	79	92

Table 16. Total number of plasma, buffy coat, and urine samples collected at 9 months follow-up in all three countries.

9 months follow-up	All	Romania	Spain	Sweden
Plasma	39	7	4	28
Buffy coat	39	7	4	28
Urine sample day 1	138	12	58	68
Urine sample day 2	142	13	56	73
Urine sample day 3	138	12	57	69

At the time of reporting, plasma and urine samples have been sent to Imperial College of London (Phenome Centre) for metabolomics analyses applying highly sensitive untargeted mass spectrometry, and buffy coat samples sent to IMDEA (Spain) to identified epigenetic signatures of birth weight and of child BMI variations based on genome-wide methylation (CpG).

The obtained molecular baselines will provide cornerstones for studying biomarkers of obesity in early-life, how environmental and lifestyle factors impact those markers, and how intervention strategies and policy implementation can influence childhood obesity at the molecular level. These baselines will enable an assessment of how the exposure and lifestyle factors can alter epigenetic/metabolomics signatures of weight variations. In these analyses, genetic differences will be addressed using a list of genotypes and haplotypes that were reported to interact with dietary intakes and differential disease risk.

Crossing the molecular data with anthropometrics, food intake, physical activity and SES data, the follow-up phase will enable us to assess the reversibility of the molecular signatures of obesity following the intervention, as well as a validation of dietary reports through the urine metabolomics assays.

Food intake

In Romania, 58 24 h-recalls were made at baseline and 22 after 9 months, in Spain, 64 at baseline and 43 after 9 months and in Sweden, 94 at baseline and 72 after 9 months. In Sweden the baseline food intake assessments have been evaluated. For Spain and Romania, the data processing will be performed after the end of the project.

Table 17 describes the energy and nutritional intake of the total group from Sweden at baseline, categorized by gender. The only significant mean difference (MD) in dietary intake between girls and boys was calcium (mg) intake (MD = 165 mg, p = 0.02). Boy's parents reported a calcium intake of 806.0 mg/day compared to girl's parents that reported 641.0 mg/day. In Table 18, the energy and nutritional intake of the children divided into groups of different weight categories was described. For comparison, age appropriate values from the Nordic Nutrition Recommendations (NNR 2012) is included (44). No significant differences were observed in mean energy, macronutrient, micronutrient, salt, or whole grain intake between children in the different weight categories. No significant associations observed between child BMI z-score and dietary intake was observed (data not presented in tables).

The differences in child energy and nutritional intake in preschool and home environments are described in Table 19. Almost 50 % of the days reporting food consumed at home were either a Saturday or a Sunday. Differences were seen in nutritional intake depending on whether the food had been eaten in the preschool or in the home. Children reporting food intake at home showed a 4.4 g lower fibres intake (p = <0.01), 166.0

mg lower calcium intake (p = 0.01), 2.3 g lower vitamin D intake (p = 0.01), 13.3 g lower whole grain intake (p = 0.01), and 1.0 g lower SFA intake (p = 0.02) compared to children reporting food intake in the preschool.

Table 17: Children's reported energy and nutritional intake, and comparison by gender-data from Sweden.

Dietary variables	All (n=90)	Boys (n=26)	Girls (n=64)	P value
		Mean (SD)		p*
Energy (kJ)	5737 (1854)	6116 (2036)	5584 (1770)	0.22
Energy (kcal)	1370 (443)	1461 (487)	1334 (423)	0.22
Protein (g)	55.4 (18.2)	60.7 (21.0)	53.3 (16.6)	0.08
Protein (E%)	16.7 (3.2)	17.2 (3.3)	16.4 (3.2)	0.28
Fat (g)	52.3 (22.1)	57.2 (24.4)	50.3 (21.0)	0.18
Fat (E%)	33.3 (7.4)	34.1 (7.4)	32.9 (7.5)	0.52
TFA (g)	0.2 (0.2)	0.2 (0.3)	0.1 (0.1)	0.11
TFA (E%)	0.1 (0.1)	0.1 (0.1)	0.1 (0.1)	0.12
SFA (g)	20.5 (9.9)	23.2 (11.4)	19.4 (9.1)	0.10
SFA (E%)	13.0 (3.8)	13.7 (4.0)	12.7 (3.7)	0.23
MUFA (g)	20.0 (9.3)	22.1 (9.9)	19.2 (9.0)	0.18
MUFA (E%)	12.7 (3.7)	13.1 (3.7)	12.5 (3.7)	0.46
PUFA (g)	7.2 (3.5)	7.1 (3.3)	7.3 (3.6)	0.78
PUFA (E%)	4.7 (1.9)	4.3 (1.4)	4.9 (2.1)	0.20
Carbohydrates (g)	161.3 (56.6)	168.2 (59.1)	158.4 (55.9)	0.46
Carbohydrates (E%)	47.9 (7.6)	47.9 (6.8)	48.3 (7.9)	0.42
Iron (mg)	6.3 (3.7)	7.3 (5.4)	6.0 (2.8)	0.13
Calcium (mg)	688.6 (297.4)	806.0 (341.7)	641.0 (265.7)	**0.02**
Vitamin D (μg)	6.6 (4.2)	7.6 (6.1)	6.2 (3.2)	0.17
Fiber (g)	14.5 (5.6)	13.1 (5.4)	15.0 (5.7)	0.15
Whole grains (g)	23.9 (26.9)	23.8 (25.7)	24.0 (27.6)	0.98
Salt (g)	5.6 (2.5)	6.3 (2.8)	5.4 (2.4)	0.13

a Age categorized in: children 2-3 years of age (≤ 3y), 4 years of age (4y) and 5-6 years of age (≥ 5y)
b Estimated for children 2-5 years of age; reference weight 16.1 kg (REE 3600 kJ/d)
c Recommended intake for children 2-5 years of age
d Recommended levels for children 1-17 years of age with gradual increase of intake with age
e Recommended upper level for children 2-9 years of age
* P-value according to independent t-Test; significance level < 0.05.
** P-value according to ANOVA; significance level < 0.05.
Significant results are in bold.
Abbreviations: Percentage of caloric intake (E%), Trans fatty acids (TFA), Saturated fatty acids (SFA), Monounsaturated fatty acids (MUFA), Polyunsaturated fatty acids (PUFA)

Table 18: Swedish children's energy and nutritional intake in relation to child weight status. For comparison, the Nordic Nutrition Recommendations 2012 (NNR) for dietary intake in children age>2 years is included (44).

Energy and nutritional intake		Child weight status categories[a°]			
		Overweight	Obesity	Severe obesity	
		n=30	**n=26**	**n=34**	
	NNR 2012		Mean (SD)		p*
Energy (kJ)	5300 kJ/d[b]	5619 (1510)	5297 (1415)	6180 (2321)	0.33
Energy (kcal)	1430 kcal/d[b]	1342 (361)	1265 (338)	1477 (555)	0.33
Protein (g)		54.6 (16.0)	51.3 (14.3)	59.3 (21.9)	0.36
Protein (E%)	10–20 E%	16.6 (2.8)	16.7 (3.1)	16.7 (3.7)	0.92
Fat (g)		50.6 (19.6)	49.5 (17.9)	55.8 (26.8)	0.70
Fat (E%)	25-40 E%	32.9 (7.1)	34.3 (8.3)	32.8 (7.1)	0.74
TFA (g)		0.2 (0.2)	0.1 (0.1)	0.2 (0.1)	0.31
TFA (E%)	As low as possible	0.1 (0.1)	0.1 (0.1)	0.1 (0.1)	0.23
SFA (g)		19.4 (8.8)	19.2 (8.4)	22.5 (11.7)	0.52
SFA (E%)	<10 E%	12.6 (3.9)	13.2 (3.9)	13.1 (3.7)	0.90
MUFA (g)		19.2 (8.5)	19.0 (7.7)	21.5 (11.0)	0.70
MUFA (E%)	10-20 E%	12.4 (3.7)	13.2 (4.3)	12.6 (3.2)	0.55
PUFA (g)		7.6 (4.0)	6.9 (2.7)	7.1 (3.5)	0.84
PUFA (E%)	5-10 E%	5.0 (2.1)	4.9 (1.9)	4.4 (1.7)	0.52
Carbohydrates (g)		158.3 (46.1)	145.9 (47.3)	175.7 (68.4)	0.24
Carbohydrates (E%)	45-60 E%	48.2 (7.6)	46.8 (8.3)	48.5 (7.1)	0.74
Iron (mg)	8 mg[c]	6.3 (2.2)	6.0 (3.5)	6.7 (4.8)	0.81
Calcium (mg)	600 mg[c]	659.2 (225.8)	664.5 (315.4)	733.1 (339.2)	0.63
Vitamin D (μg)	10 μg[c]	6.2 (3.4)	7.4 (6.1)	6.4 (3.0)	0.83
Fiber (g)	2-3g/MJ[d]	14.9 (6.21)	13.8 (5.0)	14.6 (5.7)	0.89
Whole grains (g)		24.9 (20.5)	22.0 (24.7)	24.4 (33.4)	0.94
Salt (g)	3-4 g/d[e]	5.8 (2.2)	5.2 (1.9)	5.9 (3.1)	0.76

[a] Weight status categorized according to age and sex adjusted body mass index (24)
[b] Estimated for children 2-5 years of age; reference weight 16.1 kg (REE 3600 kJ/d)
[c] Recommended intake for children 2-5 years of age
[d] Recommended levels for children 1-17 years of age with gradual increase of intake with age
[e] Recommended upper level for children 2-9 years of age
° No mean difference in age was observed between the groups of different weight status (p = 0.24).
* P-value according to ANCOVA: significance level < 0.05. Adjusted for "Sex" and "Age".
Significant results are in bold.
Abbreviations: Percentage of caloric intake (E%), Trans fatty acids (TFA), Saturated fatty acids (SFA), Monounsaturated fatty acids (MUFA), Polyunsaturated fatty acids (PUFA)

Table 19. Participating children's energy and nutritional intake in preschool and in the home as recorded in the food diaries and 24-hour recalls from Sweden.

Energy and nutritional intake	Home	Preschool	
	n=30	n=60	
	Mean (SD)		*p**
Energy (kJ)	5260 (1721)	5977 (1886)	0.08
Energy (kcal)	1257 (411)	1428 (451)	0.08
Protein (g)	48.7 (15.2)	58.8 (18.7)	**0.01**
Protein (E%)	16.1 (3.7)	16.9 (3.0)	0.25
Fat (g)	47.6 (17.0)	54.6 (24.0)	0.16
Fat (E%)	33.7 (7.2)	33.1 (7.6)	0.72
TFA (g)	0.2 (0.2)	0.1 (0.2)	0.36
TFA (E%)	0.1[b] (0.1)	0.1[c] (0.1)	0.05
SFA (g)	17.5 (7.0)	22.1 (10.8)	**0.02**
SFA (E%)	12.3 (3.3)	13.3 (4.0)	0.21
MUFA (g)	19.2 (8.0)	20.4 (9.9)	0.55
MUFA (E%)	13.5 (3.9)	12.3 (3.6)	0.16
PUFA (g)	7.2 (3.0)	7.3 (3.7)	0.90
PUFA (E%)	5.2 (2.0)	4.5 (1.8)	0.09
Carbohydrates (g)	151.3 (61.6)	166.2 (53.9)	0.24
Carbohydrates (E%)	48.3 (7.1)	47.7 (7.8)	0.75
Iron (mg)	5.4 (3.2)	6.8 (3.9)	0.09
Calcium (mg)	578.0 (204.8)	744.0 (321.7)	**0.01**
Vitamin D (µg)	5.1 (2.5)	7.4 (4.7)	**0.01**
Fiber (g)	11.5 (4.4)	16.0 (5.6)	**<0.01**
Whole grains (g)	15.1 (15.7)	28.3 (30.2)	**0.01**
Salt (g)	5.0 (2.3)	6.0 (2.6)	0.06

[a] No mean difference in age was observed between children reporting dietary intake in preschool compared to at home (MD = 0.05, 95 % CI: -0.52, 0.42, *p* = 0.83).
[b] TFA (E%) mean (SD) = 0.13 (0.10)
[c] TFA (E%) mean (SD) = 0.08 (0.09)
*** P-value according to independent *t*-test; significance level < 0.05.**
Significant results are in bold.
Abbreviations: Percentage of caloric intake (E%), Trans fatty acids (TFA), Saturated fatty acids (SFA), Monounsaturated fatty acids (MUFA), Polyunsaturated fatty acids (PUFA)

Feasibility, attrition, and acceptability of the intervention

Feasibility of recruitment

Recruitment to the ML Europe study started in 2019 and went on until 2021. We had anticipated that recruiting families of young children with overweight and obesity would take time. The pandemic extended this time further. The lockdowns in Spain and in Romania and restrictions of social contacts in Sweden, as well as the overall concerns by the families, and closed primary health care centres made recruitment come to a temporary halt. This scenario was similar across the three participating countries. Despite this delay, the recruitment obtained the needed sample size.

Barriers and facilitators in the communication with families, with important impact on recruitment, were evaluated in the 3 countries using a similar study design, inspired by the Swedish team Sjunnestrand et al. 2019 (7). In Romania, healthcare professionals (family physicians, paediatricians, and dieticians) who treat children with excess weight were invited to telephone interviews, in March and April 2020. The study

identified barriers and facilitators in childhood obesity-related communication, as perceived by healthcare professionals in Romania (8). Facilitators identified included kind language in communication and experienced motivational interviewing of the medical healthcare professionals (8). Barriers in communication were part of several layers of distrust, recognized as tension between professionals and caregivers due to conflicting beliefs about excess weight, as well as lack of trust in medical studies (8). These findings could explain the higher dropout rated in Romania, as families might not have had appropriate readiness level, to be able to cope with intensive health programs. Many families in Romania were in precontemplation level in according to 'stages of change' theory (45), as they could not recognize the children's excess weight. Furthermore, research studies, in general, were reported by healthcare professionals to have relatively low acceptance, in Romanian families (8). This could even more, explain the lower recruitment and higher dropout, compared to the other countries.

In Spain, the research team conducted a similar study using questionnaires, where they asked paediatricians about their perceptions and experiences of addressing young children's weight to parents and what they perceived as barriers for families to participate in child weight management. To make sure the important results reached the target audience, the study was published in a Spanish journal where the main readers are clinicians (9). Professionals in Spain reported that the most common reason for families to be reluctant to enrol in weight management was that parents found it difficult to recognise that the obesity in their children might be a health problem. Another barrier to recruitment was that parents felt criticized or felt shame in acknowledging their child's excess weight. The organization of health system in Spain, did not offer appropriate obesity management in children. Some nurses did not know where to refer the children, or felt that the child would not receive optimal care within a busy paediatric clinic (9). Improved communication skills for the weight management teams was considered an important facilitator for better care (9).

In Sweden, 17 child health care nurses were interviewed regarding their experiences of addressing and communicating young children's overweight and obesity to parents. In Sweden, the CHC nurses play an important role in preventing overweight and obesity in children since they regularly meet a large proportion of families with young children. Understanding the underlying factors that influence conversations about overweight and obesity in young children is therefore crucial in order to offer the best support to the families. The CHC nurses reported that a trustful relationship with the family was important when initiating conversations regarding children's weight. They asked for more training in communication skills and education in childhood obesity in order to provide better support. The organization for weight management early in childhood was considered inadequate; the nurses requested clear guidelines for what care they should provide, when they should refer to other health care professionals, and to whom (7). In Sweden, we also interviewed 17 parents about their experiences following conversations about their young child's weight in the primary health care setting, published in 2022 (46). Parents identified weight-related conversations as difficult but important catalysts for lifestyle changes. Parents felt empowered when nurses used a responsive communication style and non-blaming language, with a focus on healthy habits rather than weight. However, when nurses provided generic advice and used alarmist or judgmental language, parents felt disempowered. Parents' reactions to weight-related conversations with nurses were important, as these conversations led to lifestyle changes that entailed emotional and social challenges. These findings reveal the importance of communication skills training, with focus on childhood obesity, to all paediatric clinicians (46).

Attrition and acceptability to treatment

In order to assess the time involvement for each group the attendance of clinical visits and parent group sessions between baseline and 3 and 9 months in Romania, Spain and Sweden are showed in Table 20. In accordance with the study protocol, more sessions and time were offered to the parent groups during the first 3 months, this difference was eradicated between 3 and 9 months. High variability in attendance was seen in PG, 49.7% attended 7-10 sessions, 32.0% attended 1-6 sessions and 18.4% attended 0 sessions, see Flowchart, Figure 3. Additionally, the intensity of the parent program may also have led to more dropout than in the ST group. Reasons for dropping out was "no contact", PG n=19 and ST n=8, "declining participation" ST n=9, other less frequent reasons include, "moving", "wanting to manage on their own" and "no time".

Table 20. Attendance of clinical visits and parent group sessions between baseline and 3 and 9 months in Romania, Spain, and Sweden.

	Romania			Spain			Sweden		
		0-3 months	3-9 months		0-3 months	3-9 months		0-3 months	3-9 months
	n	median (IQR)		n	median (IQR)		n	median (IQR)	
PG	44	7.0 (8.0)	1.0 (1.0)	38	7.0 (4.0)	1.0 (1.0)	49	7.0 (3.0)	0.0 (0.0)
ST	40	2 (0.0)	1.0 (1.0)	27	1.0 (1.0)	2.0 (1.0)	60	1.5 (1.0)	2.0 (2.0)
Clinical visits (hours) between 0 and 9 months									
PG	44	8.5 (11)	0.5 (0.5)	38	10.5 (6.0)	0.5 (0.0)	49	10.5 (9.0)	0.0 (0.5)
ST	40	1 (0.0)	0.5 (0.4)	27	0.5 (0.5)	0.5 (0.0)	59	1.0 (0.5)	1.0 (1.0)

Table 21 report the perception of what parents learnt from the parental groups. With little variance between countries, most items received a mean score of 3 or above which indicate that parents most often or completely perceived the program as meaningful and relevant.

Table 21. Parents perceptions of what they have learnt and perceived was brought up during the More and Less parent groups

	Statement	Romania	Spain	Sweden
		n=23	n=30	n=24
1	I have received tips on new parenting skills/strategies to use.	3.9	3.9	3.4
2	I have become clearer when setting limits.	2.9	2.9	3.1
3	I have become better in noticing the things that my child is doing well.	3.0	3.0	3.2
4	The group leaders recognized that our children are unique and that the same strategies will not necessarily work for each child.	3.6	3.6	3.8
5	I now use new ways to help my child to cooperate.	3.5	3.5	2.8
6	We have discussed the importance of having realistic expectations for our children.	3.3	3.3	3.4
7	I have received tips in how to be clearer in my communication with the child's kindergarten/preschool/afterschool program.	3.6	3.6	3.2
8	I have become more consistent in teaching my child new things.	3.2	3.2	2.9
9	I have been made aware how children respond to lecturing.	3.4	3.4	3.2
10	I have learnt how to use rewards when teaching new behaviors.	3.6	3.6	3.2
11	We have talked about noticing even small improvements in our children's behaviors.	3.7	3.7	3.5
12	I have received tools to handle or avoid power struggles with the child.	3.6	3.6	3.5

13	The group leaders have recognized the challenges faced by parents and provided strategies to handle these.	3.7	3.7	3.5
14	During the program I have become more specific when describing to my child what I want my child to do to improve our collaboration.	3.4	3.4	3.0
15	During the program we have talked about the time it takes for changes to occur (e.g., a child needs to try new foods many times before starting to like it).	3,9	3.9	3.7
16	The material that was handed out was clear and useful.	4.0	4.0	3.8

Response options: 1=not at all, 2=sometimes, 3= most often, 4=completely

Use of the MINISTOP app

In Sweden, 38 out of 64 families (59.3%) randomized to intervention downloaded the app, in Spain, 36 out of 45 (80%) and in Romania 21 out of 44 (47.7%). However, not all started to use the app, in Sweden 57.8%, in Spain 64,4% and in Romania 22.7%. Of families that participated in the parent group sessions and received the app 28.6% (10/35) used the app in Romania, 64.4% (29/45) in Spain, and 77.5% (49/37) in Sweden. In Romania, network problems seriously affected the parents' use of the app as more than 10 families could not download the app despite significant efforts from the research team and the app developers.

In the MINISTOP app parents could register their child daily intake of vegetables, fruits, berries, sugar sweetened drinks, sweets, bakeries (e.g., buns and cakes), ice-cream, physical activity and Screen-time. Table 22 reports how many parents registered the different habits. Further analyses of this data is ongoing.

Table 22. Daily intake of vegetables, fruits sugar sweetened drinks, sweets, bakeries (e.g., buns and cakes), ice-cream, physical activity and Screen-time reported by parents using the MINISTOP app

MINISTOP Registrations	Romania	Spain	Sweden
	n=8	n=14	n=25
Fruit	8	14	25
Vegetable	8	14	25
Berries	8	14	25
Sweetened drinks	5	14	22
Sweets	4	14	22
Ice creams	5	14	22
Snacks	5	14	22
Physical activity	6	14	23
Screen-time	6	14	23

Parents reported the following about how they used the app (for 3 months):

- *We read the texts and find them useful, but we don't have any use of the register function.*
- *Used the app a lot, registered almost every day, it was fun to get green (on what they registered) and to get the medals.*
- *I register almost every day; I think it is super*
- *We used it in the beginning but then it became a stressful at work, so we put it [the app] aside.*
- Quotes from parent that did not use the app when being asked
- *I downloaded the app but never used it, felt already from the start that the tools provided during the parent groups were enough. I find it difficult to take time to use something that you don't think you are in need of.*
- *I don't think we needed the app; it has worked well anyway.*
- *It doesn't feel good when it (what they register in the app) turns yellow or red.*
- *The push notifications give me a bad conscience*

In summary, it seems that families that perceived the ML parent program to be enough did not use the app whilst families that requested more support appreciated the app. One parent reported to dislike how foods were marked as yellow or red (rather than green), possibly as if made the parent feel as bad choices were being made. To be reminded about something that you had not done, was also reported by one parent to make them feel bad. A qualitative evaluation of the app is ongoing where parents are asked about the app in greater detail.

We will continue to evaluate the acceptability of the ML program, the MINISTOP app and standard treatment of overweight and obesity management through interviews with participants.

The influence that the Covid-19 pandemic

Furthermore, during the pandemic, at all three study sites, telephone-based interviews were conducted with participating parents (n=70, representing 68 families) twice during a period of 6 months. We aimed to explore the influence that the Covid-19 pandemic had had on the families and to understand future care needs. Our analysis was informed by Bronfenbrenner's ecological systems theory, which embeds home and school-based influences within societal and policy contexts. We found that differences between sites were closely linked to differences in pandemic-related policies i.e., extent and length of lockdown, and that differences within sites often reflected differences in socioeconomic status. In most families, the pandemic had a major impact on eating habits and physical activities, but not in all families, and not always to the worst extent. Similar situations led to different experiences, depending on national contexts e.g., when parents started to work from home. Swedish parents spoke of working from home as stress reducing, allowing them to spend more time with their children, cook healthier meals, and go on walks. Romanian parents, on the other hand, spoke of working from home as stress inducing, leaving them with no time to facilitate children's activities. The difference was that Swedish schools stayed open, whilst Romanian schools did not. Parents expressed largely similar concerns about children's eating, activity, and social/emotional wellbeing across the two waves. Although, the importance of considering obesity-related changes in a wider familial, social, and environmental context has been well-known to those working within the obesity field, the interviews made it even more clear (47). This analysis has provided insights into recruitment and attrition issues during the pandemic.

7 Discussion section

The ML Europe trial assessed the impact of parent group sessions (the ML program) followed by a mHealth application (the MINISTOP app) to treat overweight and obesity in 2-to 6-year-old children from three European countries. In this trial, we included a total of 304 children, consisting in a representative sample of the study population in each participating country. Recruitment in Sweden was performed by inviting all primary and secondary health care centres in Stockholm County to participate. A similar process was performed in Spain (all primary health care centres and hospitals in Mallorca were invited to participate). However, the ability to get a representative sample of the study population in Romania was more difficult because a referral system for childhood obesity was not set up. Therefore, recruitment relied on families contacting the research team themselves through contacts with physicians and paediatricians and Facebook announcements. Therefore, certain parts of the population may have been missed, e.g., those not likely to contact the research team and those who do not use Facebook.

Additionally, there are a few other factors that were considered with regards to recruitment, as possibly influencers for the representativeness of the overall sample. Firstly, the participating families needed to be

able to understand, speak, and read Romanian, Spanish, or Swedish sufficiently well (depending on the country of participation) in order to participate. Secondly, families with low socioeconomic status and parents with a lower educational background have been observed to be less likely to participate in research (48,49). Alas, it has been observed that children of migrant parents and those of low socioeconomic status are more likely to have overweight or obesity (50,51).

Furthermore, families were included if they owned a smartphone compatible with the MINISTOP app, which could have affected recruitment of low socioeconomic families; however, we believe this risk was quite small as smartphones are so commonly used in most populations. In the ML trial, the parents decided not to participate for various reasons, with the most common being parents' work schedules or family situation (16). Using the experiences from previous clinical RCTs, we ensured that recruitment and patient participation were organized in the most feasible way, e.g., time, date and place for the parent groups will be adjusted to suit as many families as possible.

We anticipated the recruitment to be influenced by target population size, which varied between the countries (330 000 in Timisoara, 860 000 in Mallorca and 2.3 million in Stockholm County). Also, we were aware that the prevalence of overweight and obesity among children differs in each site. In Romania, a study including 6-year-old children found the prevalence for overweight and obesity was 19% (52). In Spain, the prevalence of overweight and obesity was 21% in 3 to 5-year-old children (53). In the Stockholm County, the prevalence of overweight and obesity among 4-year-old children was on average 11% ranging from 4%, in the more affluent areas to over 15%, in less affluent areas (54). Thus, although the prevalence and obesity seemed to be lowest in the Swedish site, the larger population has compensated this challenge.

The largest recruitment challenge was the Covid-19 pandemic and regulatory policies that varied from complete lockdown in Romania, to opened schools in Sweden. The lockdown temporarily and severely impacted the recruitment in Romania and caused delays in follow-up and higher dropout rates (47). Romania adopted strict lockdown for a period of 3 months, followed by restricted access to public institutions for more than 2 years (55).

Regarding children's age, the recruitment included different mean age in the three countries. In Romania and Spain, the mean age was higher than in in Sweden. The lower mean age at baseline in Sweden might have been caused by the first ML study, as that study already included children form 4-6 years old, showing a reliable local systems of recruitment, already in place. Thus, in Sweden this study was an extension to younger ages. In Romania and Spain there was no similar recruitment system.

The weight category at baseline were dissimilar in Romania and Spain compared to Sweden (53.6%, in Romania and 62.2% in Spain, compared 39.2% in Sweden). Higher percentage of severe obesity were included, in both, parent and standard treatment, in Romania and Spain; suggesting that families were motivated to participate in treatment mostly when there were complications of obesity and/or stigma, as shown in the interview with healthcare professionals (8).

In the preliminary country analysis, the BMI SDS change from baseline to 9 months, was significantly improved for the PG compared to ST only in Sweden. In Romania, a decrease in BMI SDS was observed in both parent group and standard treatment, yet a significant difference between groups was not observed, probably due to lack of statistical power. Notable differences in attrition to sessions and clinical visits as well as in dropout rates within and between the 3 countries, and between study arms will be carefully analysed, to explore possible causes. Socioeconomic factors were likely relevant factors contributing to dropout and to what extent families could attend sessions and clinical visits. Although the ML program delivery was

flexible, work obligations may have been incompatible with the session's timetable. Other cultural or religious factors could have been involved in attrition to treatment. A review investigating attrition barriers showed that the presence of comorbidities, higher BMI, behavioural issues, vulnerable families (i.e. racial/ethnic minorities, poor and single-parent households) and treatment that does not meet the families' expectations or schedule, seem to be at risk factors for dropping out (56). A recent mega-ethnography (review-of-reviews) showed that children and family participation in obesity management services was modelled by their acceptability, and perceived benefits and expectations. Completing an intervention was determined by its perceived success, beyond just weight loss, including behaviour change, enhanced self-esteem, and the delivery of support (14).

Strengths and limitations

The randomized controlled design and multi-site recruitment (i.e., Timisoara, Romania; Mallorca, Spain and Stockholm, Sweden) are strengths of this study. Furthermore, the fairly large sample size (n = 304) allows assessment of the intervention's effectiveness in samples within and across three very different European countries. The young age of the children is another strength of the study, as few studies have previously endeavoured into interventions in children below 4 years of age. Only 7 other studies for obesity treatment have previously included children under 4 years (57–62). The combination of group sessions followed by a previously evaluated mHealth app is a further strength, as it allows for the reiteration of the material taught during the group sessions to be explained in different ways with different examples. This is important, as the booster group in the initial ML study had a mean change in BMI SDS from baseline which was significantly larger in comparison to standard treatment and the group without boosters (-0.54, $p< 0.001$; -0.11, $p =0.551$; and -0.04 for the booster, without boosters, and standard treatment groups, respectively) (16).

As family structures and socioeconomic demands in contemporary families are dynamic, fathers and or grandparents are more actively engaged in meal preparation and feeding of the children, thus research studies should include their involvement in nutrition and feeding practices (63–65). Although the project addressed the family as an entity, the study is limited, considering the intervention was provided directly to more mothers, than fathers and grandparents. This study was also limited by the fact that there is no standard overweight and obesity treatment across Europe. Therefore, the control group received different treatment depending on the country of participation, which could have influenced the results. However, standard treatment as per country is the best possible control, as it would be considered unethical to withhold treatment for a condition if a treatment exists (66).

The use of objective assessments for anthropometrics and body composition, physical activity and sedentary behaviour, food intake, as well as epigenetic and metabolic markers is a further strength of this study. Additionally, the use of qualitative methods, i.e., semi-structured interviews with health care professionals and parents from all sites allow the feasibility assessment of this new overweight and obesity management intervention, in three European countries.

8 Conclusions

In the majority of countries, there is no standard management of overweight and obesity in the preschool years. As overweight and obesity in preschool age may track into adolescence and adulthood, causing psychological and physical consequences, families should receive support as early as possible. Feasible and effective approaches for families with preschool aged children should therefore be prioritised. This study shows that the More and Less intervention (parent program and mHealth application) was accepted by

families and caregivers in three countries: Romania, Spain, and Sweden. Our preliminary results show that the program was effective in decreasing children's BMI SDS compared to standard care in Spain and Sweden. In Romania, decrease in BMI SDS was observed in both parent group and standard treatment, yet a significant difference between groups was not observed, probably due to lack of statistical power. Overall analysis of results is needed, in order to establish if the ML program has the potential to be implemented into routine care where a structured weight management program for young children. The MINISTOP app may serve as a follow-up support for sustained effects of care for some families but not all.

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Authors' contributions

All authors were involved in the study design for More and Less Europe. AE is the project coordinator for the three sites and drafted the manuscript together with CDN who also aided in the development of the MINISTOP app's content. ACE is the primary investigator for the Romanian site and JAT is the primary investigator for the Spanish site. Regarding recruitment and data collection KN is the coordinator in Sweden, CLS in Romania and EA and CB in Spain. JAM is responsible for analyses of epigenetic and metabolic markers and their interpretations. GF and IGP are responsible for the analyses of gut hormones and validation of food intake through urine. MS and MB are responsible for statistical analysis. ML created the original MINISTOP program and led the work when it was modified for ML Europe. PN is responsible for the Swedish site and the primary investigator of the ML Europe. All authors read and approved this version of the manuscript.

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